Attorney General Alliance

2020 – 2021 CHAIR'S INITIATIVE WORKING GROUP OUTLINE

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Table of Contents

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I. Introduction and Background

Starting in October, the Attorney General Alliance, led by our Chair – North Dakota Attorney General Wayne Stenejhem – set out to force a dialogue between the state's best and brightest legal minds and the private sector about issues related to an eventual COVID-19 vaccine. There was no approved vaccine when the project began, and most assumed a vaccine was unlikely to be approved in calendar year 2020. That is, the issue was – and remains – fluid and uncertain. A great deal about a vaccine response to COVID-19 remains a work in progress, and it is begrudgingly accepted that such ambiguity will remain the norm for months (even years) to come. Regardless, state Attorneys General are leaders that citizens turn to for reliable answers during times of insecurity.

The Attorney General Alliance developed five areas of interest to focus upon:

- Multiple approaches of a vaccine;
- Prioritization of vaccine administration;
- Consumer protection;
- Constitutional considerations; and
- Antitrust considerations.

Each focus group was led by a bi-partisan pair of states. All five "cohorts," as they came to be called, also included representatives from private industry. Over the course of five weeks, more than 25 calls occurred involving participants from more than 30 states and dozens of companies. Each call was moderated by AGA staff to ensure the cohort stayed reasonably focused on its mandate, but participants were encouraged to be frank and to engage in thought leadership. Calls occurred weekly, were unrecorded, and participants all engaged with each other directly.

This effort was not a legal review, but it forced state attorneys to focus on the complex, yet critical issues presented by a vaccine response to a pandemic. Many topical issues were not discussed and could be brought up during future engagements, including but not limited to: health data privacy during a pandemic; telehealth during a pandemic; contact tracing and geolocation; denial of care and triage; mandatory quarantine measures; mitigation measures (such as full and partial closures or mask mandates); drug treatments; distance learning and myriad others.

What follows is an informal synopsis of the cohort discussions, including remarks about consensus where it existed and to dos for consideration. The actual discussions were much broader than what is noted here. This document will be amended as discussions continue and should not be relied upon as a final or definitive statement. If you have questions or are seeking additional information or reference, please contact:

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II. Vaccine Methodologies and Legalities

Led by Idaho and Washington.

Cohort I, the Vaccine Methodologies and Legalities cohort was led by Idaho and Washington. The participants focused on the scope and application of the Prep Act to state authorities.

Public Readiness and Emergency Preparedness Act (Prep Act)

The Prep Act is a federal law put in place to address certain emergency health crisis. In general, it grants authority in the Secretary of Human and Health Services (HHS) to create civil immunity for certain actions related to "covered countermeasures" in response to a disease, health condition, or other threat to public health, like a pandemic. The statute is sweeping in its breadth and preempts state and federal statutes that might conflict with its application in the context of a PREP Act declaration. The Secretary of HHS issued the first Prep Act declaration for COVID-19 on March 10, 2020. The various declarations and guidance documents can be found on HHS's website: www.HHS.gov or by clicking here.

There are several steps that must occur for Prep Act liability protections to apply. First, a qualifying emergency must be declared. Next, the Secretary must issue a declaration that the Prep Act applies. Once the declaration is made, the Act applies to "covered persons" during the administration of a "counter-measure" – both terms are defined by the Act, the declaration, and subsequent guidance. Any analysis of Prep Act applicability must start with the Secretary's various orders, as amended, and related guidance,[1] which itself has several terms open to interpretation, such as "recommended activities" and an "Authority Having Jurisdiction."[2]

A "covered person" in the context of the COVID-19 pandemic includes U.S. manufacturers and distributors of a vaccine, but also "program planners" which likely includes federal, state, local and tribal government employees that supervise dispensing programs, logisticians, and individuals (and companies) actually issuing shots to patients. It is less clear whether personal protective equipment and vaccine supply chain providers enjoy the same liability protections, but the cohort believed a good faith action to facilitate distribution of the vaccine or protect against the disease would enjoy a colorable argument to immunity. "Willful misconduct" is not covered as it is defined (narrowly) by the Act itself. All matters arising under the Prep Act are

[1] The fact that some federal assertions came in the form of guidance documents or advisory opinions, rather than formal declarations or direct statutory authority was noted by cohort participants. Reliance on guidance documents for policies such as expanding PREP Act coverage to unlicensed pharmacy technicians places such policies on less defensible grounds as guidance documents are not primary law. Nonetheless, the statute places a great deal of discretion in the administrators of the Act, and therefore guidance documents would likely be viewed by a court as compelling.

[2] An interesting, and perhaps beneficial use by states of the Prep Act was discussed. HHS designates states as "authorities" under the Act and therefore, a state may itself be able to use this federal designation to its own benefit in situations where state law may not fully empower the executive branch to act or to immunize state actors or agents as qualified persons for purposes of immunity.

subject to exclusive jurisdiction in US District Court in the District of Columbia by a three-judge panel.

The scope of immunity covers "all claims for loss"[3] and clearly supplants classic examples of state tort law. There is very little case law on the Prep Act as its use has been limited since its adoption. The law is clearly designed to have a broad application and to be interpreted liberally, but the scope is not endless. There is, for example, an open question about whether the Prep Act would pre-empt state consumer protection statutes (if they applied to the dispersal of a vaccine) or state anti-trust statutes (if vaccine companies where found to be engaged in anti-competitive collusive behavior, for example). It is also unclear if Prep Act liability could be asserted to defeat a due process or equal protection lawsuit, though such a defense may be unnecessary if the governmental activity subject to such allegations satisfies more traditional rational basis or even heightened scrutiny, which they likely would.

The Prep Act is very likely to be litigated repeatedly over the next several years.

Certain key terms in the Prep Act include:

"Covered Person" (42 U.S.C. § 247d–6d(i)(2)):

The term "covered person", when used with respect to the administration or use of a *covered countermeasure*, means-

(A) the United States; or

(B) a person or entity that is-

(i) a manufacturer of such countermeasure;

(ii) a distributor of such countermeasure;

(iii) a program planner of such countermeasure;

(iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or

(v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

"Covered countermeasures" (42 U.S.C. § 247d–6d(i)(1)) includes:

(A) Qualified pandemic or epidemic products [which includes products intended to diagnose, mitigate, prevent, treat, or cure any pandemic or epidemic]

(C) A drug, biological product or device authorized for emergency use…

"Willful misconduct" (42 U.S.C. § 247d–6d(c)(1)):

- means an act or omission that is taken
  i. intentionally to achieve a wrongful purpose;

[3] 42 U.S.C. § 247d–6d(a). "Loss" is broadly defined to mean "any type of loss," including (i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of such injury, including medical monitoring costs; and (iv) loss of or damage to property, including business interruption loss. *Id*.

ii. knowingly without legal or factual justification; and
iii. in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

Willful misconduct resulting in death or serious physical injury is not covered by the Prep Act, and the burden of proof for any alleged misconduct and injury falls to the plaintiff by a clear and convincing standard which shall be construed as establishing a standard that is more stringent than a standard of negligence in any form or recklessness;

Prep Act Pre-Emption of State Licensure Laws or Regulations

A significant portion of the first Cohort's time was spent considering whether the Prep Act pre-empted state laws in the context of a declaration. Of particular concern, for example, was whether the Prep Act's liability protections extend to unlicensed pharmacy tech's who might be asked to administer a shot, i.e. acting outside their state granted professional scope of practice. To put it another way, are state licensure laws or regulations preempted? And if so, does the regulatory body have any enforcement mechanism available to it?

The cohort did not arrive at a consensus. There seemed to be widespread acknowledgement that the Prep Act would likely be understood to pre-empt less egregious activity that might normally run afoul of the strict application of licensure review.[4] That is, an unlicensed tech who skillfully and successfully administers an otherwise lawful vaccine shot during a period of high demand and low/withering supply would not be a good test case. But it was also widely accepted in the group that such a rule was unlikely to be applied in a ridiculous manner. A veterinary technician giving a "leftover" shot to a friend using a horse syringe probably cannot wrap themselves in Prep Act protection. But many tougher cases remain in the middle of these extremes and enforcement actions will be informed by: emergency declarations and authorities; supply and demand; allocation guidelines; quality of care; degree of injury (if any); transaction payment; risk disclosure; and others. In short, to the extent consensus was reached, the cohort agreed that some form of discretion by the government agency would be exercised, and that it was likely that virtually every state would face this line drawing challenge. Attorneys simply voiced concerns that enforcement decisions should not be made arbitrarily.

The sweep of the Prep Act should be understood in context and is perhaps limited by its pragmatic application, if not by the actual letter of law. That is, it may be extraordinarily broad and may indeed pre-empt state statutes, but it is limited in a few important respects. First, it applies in the context of this pandemic; it does not apply to all circumstances or for all vaccines. Second, liability protection must be rooted in the PREP Act Declaration, which, aside from state-licensed pharmacists and pharmacy interns under certain conditions, has not authorized others

[4] See also a recent case in Pennsylvania, *Gustafson v. Springfield, Inc.*, ruling the federal Protection of Lawful Commerce in Arms Act (PLCAA) of 2005 was unconstitutional under the 10th Amendment of US Constitution. Link here: Pennsylvania appeals court rules gun industry protection law unconstitutional - JURIST - News - Legal News & Commentary

to administer vaccines beyond individuals already authorized to do so under state or federal law. And while the country is in crisis, we are not yet to the point of asking veterinarians (or attorneys) to become sua sponte human doctors. If we do get to that level of crisis, the cohort agreed that government agencies should be providing increased guidance. Third, it is temporary, generally expiring at the conclusion of the public health emergency and no later than October 1, 2024. Even if the Prep Act trumps state statutes, it does so in a limited way, for a limited time and is justified by an emergency health crisis on the national (not just on the state) level.

COVID-19 Vaccine Injury Compensation

Notwithstanding the sweeping liability protections of the Prep Act, there is a means to recover losses for persons harmed by a vaccine (or covered countermeasure). But the long established Vaccine Injury Compensation Program is not the path. Instead, the Prep Act itself has an administrative injury compensation program known as the Countermeasures Injury Compensation Program (CICP). Additional information on this program can be found here. Under the CICP, anyone claiming an injury from the application of a covered countermeasure must file under this program where reimbursement of medical expenses, money for loss of employment income or survivor benefits is funded by the federal government through HHS.

The cohorts discussed how the public might be informed about the existence of this federal program and how to access the fund should they experience an injury as a result of a vaccine. Indeed, language could be vetted by states and considered for insertion in information provided at the time of inoculation (and available more generally) as follows:

> If a health risk does occur that is caused by the vaccine, you may be able to obtain compensation for your economic losses caused by that risk from a designated federal fund, but not through litigation. Additional information about this program can be obtained by contacting [insert state or federal agency information] or the Countermeasures Injury Compensation Program (CICP) at https://www.hrsa.gov/cicp or 1-855-266-2427 (1-855-266-CICP). There is a time limit to file a claim for compensation.

Such language could have several benefits, including elevating informed consent, decreasing misinformation, facilitating the sharing of information about the vaccine program. It is unlikely inclusion of such information would significantly discourage the public from receiving COVID-19 vaccinations.

Private Sector Participants

The cohort also discussed the Prep Act's application to private sector actors who are involved in the vaccine rollout. For example, many national pharmacy chains have contracts with the federal government to receive and offer vaccines to the public, and private shipping companies will deliver the frozen vaccines to locations in each and every state. While it was understood

that immunity for private actors was different than it would be for states, there was consensus that the private sector, acting in good faith, was entitled to a clear and coherent scheme under which they could knowingly make decisions. It was also acknowledged that such a clear and concise plan was not available from the federal nor any state government as of early December. The private sector is self-interested in being a successful partner in any national strategy, but they need clear guidance if they are to be asked to shoulder the burden; they cannot be exposed to unwarranted and unpredictable litigation risks. Put simply, there is a desire for consistency.

A concern was raised, but left unresolved, about the extent to which the government can coopt business and private sector actors to manage government policies; for example, implementation of a mask mandate, or making material decisions about vaccine prioritization. On one hand it could be deemed a regulatory taking. Consider having to pay a rural pharmacy tech to travel to a major city to receive a vaccine. It was also pointed out that the obligation to comply is stronger for those entities that are regulated by government, i.e. restaurants. Would it be a license violation if a business failed to comply with a vaccine mandate?

To Dos:

- The cohort suggested that perhaps states and localities should approach pandemic response with more of a "facilitating compliance" approach versus an asserting of control or attempt to compel cooperation approach. It was understood some would not buy in, but attempting to force obedience when everything was new, fluid and unknown was deemed an impossible task.
- The cohort deems it an important initiative to engage directly with the HHS General Counsel – previously Robert Charrow and Acting General Counsel Dan Barry. It is possible that opening a dialogue about the federal/state issues involving the Prep Act, especially its scope of application, may not only assist in resolving known unknowns during the COVID-19 pandemic, but also in resolving questions about the acts use in the future as well.
- A public resource – akin to a Wikipage for COVID-19 related state litigation – was recommended at one point during the discussions. The cohort's discussion demonstrated time and again that states have common experiences, yet their laws are different enough to suggest different response, or even outcomes. Nonetheless, a common resource, which would require little resource allocation by any one state, would be a welcome source of information.
- In locations where state law may conflict with Prep Act authorities, the cohort deemed it worth considering a pro-active approach where state guidance is issued. Regardless of the ultimate outcome, a pro-active approach would strengthen the states position during litigation.

The cohort leaders would like to thank Victor Schwartz and Cary Silverman at Shook, Hardy and Bacon for their time and invaluable insights.

Resources:

- link to the HHS information page on Prep Act - (https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx)
- PowerPoint that provides basics on the AICP phased approach for distribution.
- Association of State and Territorial Health Officials (ASTHO) https://www.astho.org/
- CRS paper on the Prep Act (link here).

III. Prioritization of Vaccine Administration

Led by New Mexico and Alaska.

AG involvement in Planning

State attorneys were not intimately included in the creation of most state CDC micro plans for distribution. These micro plans are the primary scheme by which states plan how COVID-19 vaccines will be distributed in their states. While true that the plans attempted to anticipate every minute detail, like much of the pandemic response the process was controlled largely by health officials with less intra-agency involvement than a normal vetting process may invite. It is unclear whether a lack of interagency cooperation will create issues, especially legal issues, as they attempt to administer the plans. Of course, any attempt to engage in a full (i.e. normal) interagency processes would likely have slowed the development of the plans and would have had concrete consequences.

First Responders and Tribes

This cohort initially sought to ensure that first responders and tribal groups would be highlighted in any response plans. The cohort, however, determined that tribal groups and first responders, including healthcare workers, were being considered a priority in all states and at the federal level. In addition, while both the federal approach and many states' micro plans lacked detail, the approach was deemed unobjectionable. That is, allocating the federal supply of vaccines to the states, without fees and without federal requirements, and on a pro-rata basis by total population was as good an approach as any other considered.

The group therefore turned its attention to other issues, including how to determine what an "essential worker" is for purposes of prioritization, ensuring rural areas of states are treated equitably, and also what legal challenges could be encountered if down-tier groups objected to the allocation schedule.

Rural

As with other aspects of prioritization, the debate and decision making were handled by health authorities and based largely on policy rationales at both the state and federal level. While debates were ongoing about which population might be moved into higher priority strata, certain groups were generally being prioritized consistent with federal guidelines. The basics seemed consistent: 1) health care workers would be early recipients of any approved vaccine; 2) healthy adults in non-essential businesses would likely not be early recipients; and 3) how states allocated everything in-between, so long as it was rationally based, would likely survive legal scrutiny. Criticism of any approach was certain. Regardless, the cohorts were comfortable that certain at-risk populations, ethnicities, special populations (such as prisoners), etc. were being considered along with the logistical challenges and availability. While the federal

government has the military infrastructure as a reliable backbone, states lack the same reliable web of infrastructure and instead seem to be relying on historical vaccine distribution methods for the COVID-19 response.

If was, for example, deemed reasonable and likely to survive a legal attack from a prisoner if other groups, such as the elderly or essential workers, received the vaccine before prison inmates. Likewise, to move populations of confined persons – as was the case with elderly housed in full-time nursing facilities – up in priority in light of infection rates was also a reasonable decision. That is, because the vaccine is so limited in supply and the need so great, as long as the decision could be explained and justified, it would likely be adequate to survive a due process or equal protection challenge. Certain more nuanced arguments, like a 6th Amendment challenge in the context of a prison inmate, were acknowledged as issues to be examined more deeply. Likewise, it was understood that as times goes on and as vaccine availability increases, drawing lines between those that receive the vaccine and those to whom that opportunity will be denied by government action will become less important.

Vaccine wastage was deemed unacceptable. While cohorts were comfortable that rural areas were being consider appropriately in planning, it was acknowledged that hiccups would occur. If overcoming logistics of delivery to, or allocation in, rural areas creates waste, such waste would not be acceptable, and solutions would need to be identified quickly. Such situations were fact specific and did not lend to deep dialogue or problem solving.

Role of Private Institutions and Essential Workers

It was surprising, though perhaps obvious, that states expect to rely heavily on the private sector to implement vaccine administration. In the early stages, government will not be in a position to adequately anticipate which parts of each business will have persons that might qualify. Even obvious initial phase businesses, like hospitals, will still need to separate those employees that would qualify during initial roll-out, such as an intensive care unit janitor, from those that need to wait for vaccine to be more widely available, like a scheduler for a plastic surgeon. Such decisions about essential businesses, including grocery stores, universities, and production facilities, become even more complex and impossible for government to make.

Businesses, at least those participating in the cohorts, had to a great degree anticipated this reality and had begun to process the task internally. But businesses were still seeking clear guidance on what regulators believe would count as an early phase qualification, and what constitutes a disqualifying factor. The industry had many concerns, but chiefly two: safety for employees, and assurance that they are not exposed to private litigation for good faith attempts to comply with ambiguous government guidance. Guidance to date was deemed too vague. Business and government participants recalled with disdain the early months of the pandemic and the efforts to both establish and adhere to “essential business” guidance. The chore of choosing certain employees who might qualify for early vaccine doses is daunting, and fear of public or government criticism for making a poor choice (especially in hindsight) was palpable.

In this context, it was suggested that perhaps an ad-hoc public/private partnership could be embraced where more granular guidance, suggestions or best practices could be shared without delay or fear of retribution that a formal regulation might carry.

Essential Workers

A reliable definition of what is an "essential worker" remains elusive. The concept varies depending on who is asked, the context and geographical location. Indeed, it is clear that further discussion of this issue is critical as vaccines continue to be distributed nationally.

All the states and business participants acknowledged that there is a patchwork understanding of the term arising from state shelter-in-place orders, issued in the spring of 2020, and COVID-19 testing approaches. However, all participants also acknowledged that approach, which was more often than not industry specific, would not directly translate to good public policy for allocating vaccines. For example, an IT systems manager of a bank whose job could be done from home but who might have needed to report to a physical location to reset servers (without interacting with any other people) clearly fit most state guidance, the basic guidance from AICP currently available or CISA essential worker definitions. But further assuming that the same individual was a 35-year-old Asian male in perfect health would not be a prime candidate to front load for a vaccine. Even more detailed essential worker classification schemes, like those adopted in Pennsylvania, failed to take into account significant factors that would make vaccine prioritization most appropriate. It was acknowledged that it is governments roll to prioritize vaccines, especially if such prioritization may include making choices that involve ease of access, living arrangements, population density, and socio-economic factors like race, ethnicity, age and other protected classifications.

Prisoners

The cohorts did discuss prioritizing prison inmates and staff but did not arrive at any specific conclusions. Of note, however, was whether private or contract prisons would be prioritized differently than juvenile, state, or federal detention centers. The participants acknowledged these questions would be challenging, and an analysis would need to be factually specific to arrive at any overarching approaches.

Unskilled Vaccine Administration

A concern exists that at some point, during later phases of vaccine allocation, the supply may in fact be greater and demand high enough that it will outpace the number of skilled professionals who can administer a shot. The cohorts did not seem so concerned about this actuality – it arose in Prep Act authority also – as to spend much time considering a logistical conclusion. First, cohort states reported that this concern was under consideration by the health experts in the state. Second, the basic rule of thumb arose that if the individual administering the shot wasn't

already in the legitimate health care system (for example, they could not bill Medicare/Medicaid), then it was perhaps a scam or unauthorized to begin with. Next, from a legal perspective, it would seem to be better practice to have a shot administered by a trained professional (even if that training was emergency and short-term to deal with a crisis) than to sweep in just anyone, even if that meant minor delays. This was a bright line most agreed should be maintained. Moreover, the system was already showing itself to be fairly elastic in absorbing the demand on pace with supply for things like COVID-19 tests. Nobody believed waiting times would be entirely eliminated, but nobody was willing to suggest attorneys administer vaccine shots either. And, in some states (especially with large rural populations) it may be that summary training for certain individuals, like EMTs, could increase the number of locations where vaccines could be administered safely. It was also believed that vaccine dosages would be forecasted far enough in advance that such supply/demand inequities would be identified in a more timely manner, as the source of the vaccine is singularly the federal government in this instance.

Law Enforcement Coordination/Security

The states agreed there was a large variation among states when it came to keeping vaccine supplies secured. Most states have included law enforcement in planning, but few expected vaccines to be guarded beyond normal procedures for keeping physical storage of sensitive drugs safe from diversion.

To Dos:

- An independent and confidential legal review of each state's micro plans and a principal-to-principal offer in each state to the Governor's lead for pandemic response to permanently assign an attorney for all issues related to vaccine administration, for such an attorney to be available (even embedded) for any small or senior meetings, for review of policies and regulations or to advise on any questions that may arise.
- Continue to discuss and address state vaccine prioritization guidance for private business regarding what qualifies as an essential worker.

IV. Consumer Protection Issues

Led by South Dakota and Nevada.

Misinformation

By far, the most central issue this cohort discussed was information. The allocation of vaccines is not a classic consumer transaction, but participants believed consumer protection laws do apply. Consumer laws would be particularly applicable to scams, black-markets and disinformation campaigns designed for profiteering. Criminal sanctions were mentioned often for the same behavior.

The subject of vaccine confidence was discussed often, and a clear consensus existed that Attorneys General do have a role to play in advocating for COVID-19 vaccines. As trusted public officials, their voice was deemed an important aspect of a larger effort to increase vaccine participation. The communication strategies suggested varied from public/private efforts, public service announcements, appearances, social media and press releases. While an AG couldn't (or shouldn't) speak directly to the health aspects of a particular vaccine, their endorsement of vaccination as the most viable path to stemming the pandemic was important to participants.

As attorneys, participants were keen to avoid suggesting that speech in opposition to vaccines should be confused with vaccine mis- or dis-information. The former was acknowledged as healthy skepticism that could be combatted adequately with clear and concise consumer education, transparency, targeted outreach and aggressive defense of the government and private institutions designing the allocation plans. But, while speech is protected, information sharing designed to dupe individuals or trick them – especially if there was a profit to be realized – would not be tolerated and deserved regulatory attention. Participants thought being proactive was important. Indeed, by focusing on the provable facts in any situations, evidence from vaccine experts and the companies themselves, many suspect that such claims could be proven or disproven.

Black/Gray Market and Counterfeit Vaccines

A lesson learned from PPE distribution the cohort felt was important to adopt for purposes of vaccines was to be very transparent about distribution channels and who is authorized to receive and administer vaccines. In the context of the crush of PPE scams early in the pandemic (for example the 3M N95 masks), it has been reported that scams were easily identified because 3M had control of its production and distribution network. Thus, it was easy to identify scams because bad actors could be more easily isolated. Another important lesson from the PPE scams was that cooperation with the company enhanced enforcement efforts, as the company had detailed information not readily apparent to state procurement officials (or bad actors). Even though vaccine distribution in the US should be more controlled than normal

market commodities, state Attorneys General must establish a direct dialogue with vaccine manufacturers to defeat black market opportunities.

Cohort offices fully expect a glut of scams related to COVID-19. Indeed, a black market of fake vaccines has already been identified by Interpol. Consumer protection offices must be on high alert over the course of the next year to ferret out bad actors preying upon citizens, families and businesses interested in keeping their loved ones safe. Many offices have and will continue to take a pro-active posture seeking to identify and stop false claims, but most offices will be forced to respond to consumer complaints – resources are simply not available to be pro-active. This of course means that every dollar spent in socializing these issues to the general public and educating consumers about the vaccine is a critical approach for all Attorneys General. Indeed, the cohorts agreed that proactive consumer education is key, and the collective AG community might be even more effective in getting out the message than just AGs acting individually.

An interesting issue that this cohort discussed related to what the media termed a "black market," but was really more about privilege or access fraud. That is, people who fabricate health risks or manipulate the system so it appears they qualify for an earlier vaccine than they would objectively receive. Cohorts agreed this was not a true black market and believed it was the role of the health departments or businesses to manage and regulate such behavior. It was not really a consumer protection issue. It might be a fraud, but given the likelihood of certifying oneself as qualified to an administering authority, it seemed as though lying would be caught. But expanding consumer protection laws to ask AGOs to gather medical information or second guess a business decision seemed an overreach. Again, the preferred approach was to issue clear guidelines early after consultation with businesses and seek to enforce those guidelines within existing resources. Also, the cohort deemed public shaming (for those that forgo a vaccine) or asking neighbors to "report" on each other as a poor enforcement program.

Price Gouging

There was no information about vaccine "price gouging," but vaccines were expected to be free for at least the foreseeable future, so anybody selling vaccines would invite attention from law enforcement. Additional protections against price gouging were understood to be a given because distribution will flow through the federal government, primarily to state governments. Given the scarcity of the resource, cohort participants believed these problems would most likely be handled criminally rather than from a consumer protection perspective.

Vaccine Confidence

Along with the proactive consumer education initiative, Cohorts believed it would be valuable to have Attorneys General also advocate pro-vaccine messages. Such a considered effort would increase vaccine confidence as AGs are seen as trusted senior public policy officials. There was a significant fear among cohort participants that the percentages of people that would trust the

safety of the vaccine could be low – below 50%. Given the massive effort required to achieve herd immunity – upwards of 75% – all public officials were expected to engage. AGs also were identified as potentially being able to address certain arguments from vaccine skeptics as being illegal (not just a difference of opinion); health officials might be seen as self-interested or not credible from a legal perspective.

The cohort discussed and generally deemed direct payments to receive a vaccine as bad public policy.

The cohort leaders would like to thank Haley Schaffer and Colette Durst from 3M Company for their time and invaluable insights.

To Dos:

- Creating a public-private partnership to educate consumers on black market, gray market, prioritization, scams and legitimate distribution to include joint op-eds, webpages, classic and social media campaigns, etc.
- Seek to improve information sharing directly with the AGO at all levels of government, including international, federal, state, county and local/city. Perhaps an AGO liaison should be established for each of these institutions to ensure someone is monitoring information flow or can be tasked to established regular contact.

V. Constitutional Concerns Surrounding COVID-19 Vaccine

Led by North Dakota and Colorado.

Federalism and State Authority

There were a number of threshold questions to be addressed by this cohort. First, does the Federal government have absolute control over administering the vaccine program. The consensus was that the Federal Government does not have absolute control due to the state's authority to manage the health and well-being of its citizens through the police power provided by the Constitution. However, the Federal Government does likely have the power to prioritize itself. This is important, because they could – likely through Executive Order – prioritize vaccination of the military before the general population of the states. It could also, as the new administration has suggested it will, mandate masks in federal institutions like federal buildings. More interesting questions begin to arise about compelling, for example, a court appearance and in turn requiring proof of vaccination before one enters. Or, whether vaccination requirements will be imposed for persons boarding planes, especially if the vaccine remains limited and prioritized. While the cohort touched on these issues, it did not delve into them deeply as it appeared the federal government intended to be deferential to state distribution plans.

Second, the cohort considered the balance of authority between the federal government and states. Neither is in control and the vaccine distribution will have to be part of a cooperative effort. "Cooperative federalism" refers to the concept that the federal government and the states are not merely separate entities, but are instead, interdependent governmental authorities . Ideally, a strong system of cooperative federalism provides for the "sharing of regulatory authority between the federal government and the states that allows states to regulate within a framework delineated by federal law." In this instance, because the federal government owns, or contracted for exclusive access to initial doses of all vaccines, they do indeed have a disproportionate amount of control over initial allocations. The cohort believes the federal government likely does have the power to attach "strings" to any free allocation of vaccines pursuant to the Spending Clause of the Constitution. For example, if the federal government chose to require states to impose a mask mandate in exchange for full and unfettered access to vaccine shipments, it likely has that authority so long as the Federal Government can make a connection between the mandate and the federal vaccine distribution program. See, e.g. *South Dakota v. Dole*, 483 U.S. 203 (1987) (requiring "reasonable conditions relevant to federal interest in the project and to the over-all objectives thereof"). Examples of the federal government imposing restrictions around federal funding occur when the Federal Highway Administration withholds federal highway funds and implements diversionary sanctions to force states to use highway funds for safety purposes as a means of compelling states to adopt traffic safety policies. If the Federal Government were to attempt to attach such restrictions to vaccine distribution, it could be attacked legally, , however given the Federal Government's current deference to state's programs for receiving and allocating vaccines, the

cohort did not conduct a deep analysis into legal challenges states could present. That is, the federal government has thankfully not invited this fight. Central to the idea of "cooperative federalism" is the premise that the federal government not use its authority to coerce states into acting as its agents. See *New York v. U.S.*, 505 U.S. 144 (1992). However, if the Federal Government does impose restrictions associated with vaccine distribution, states should consider several factors when deciding whether a legal challenge is appropriate. Factors considered by the cohort include, but are not limited to: whether all states are being treated the same, the connection of the restrictions to the federal program, what special classifications are impacted, the specific applicable Congressional mandate, the primary legal authority being relied upon, and the level of compliance with the US Administrative Procedures Act.

Next, given the lack of federal mandates or direction to states, the cohort considered the scope and authority of the states over its vaccine distribution programs. To date, most states have relied heavily upon emergency health statutes that grant broad authority to their executive branches to ensure the health and safety of citizens. These emergency health statutes, upon which the majority of state's executive orders rely, will continue to be central to any analysis. With relatively few exceptions, courts have been deferential to states' exercise of these authorities. Over time however, these authorities may begin to appear less crisis driven and more control by fiat. Because of this possibility, reliance on emergency health statutes may not be an adequate means by which states can enforce public health mandates as it relates to COVID-19. Mandates supported by emergency health statutes have, and will, continue to be tested and reviewed by courts. Indeed, with the return of state legislatures in the Winter/Spring 2021, deference to state executives is sure to be revisited. The cohort discussed that the degree to which legislatures limit or restrict emergency powers could be dictated by the prudence executive departments demonstrate in using their emergency powers in response to the pandemic.

The cohort further discussed that state legislation could be a way for some states to reinforce executive authority depending on the political climate of the state. At a minimum, it was discussed that when appropriate, executive action must be aggressively defended under the generic grants of emergency health authority as reasonable and rationale. Indeed, the overwhelming number of court cases challenging executive authority since the pandemic started have been successfully defended under rationale basis review. *See* e.g., *Calvary Chapel Dayton Valley v. Nevada*, No. 19A1070; *Elim Romanian Church v. Illinois*, No. 19A1046; *Southbay United Pentecostal Church v. California*, No. 19A1044. States must be mindful to tread lightly where certain special considerations are present, including but not limited to race and ethnicity, age and religion. See *Oregon v. Smith*, 494 U.S. 872 (1990).

The cohort believed that as a general matter, while governors would indeed have the authority to mandate vaccines for its citizens pursuant to the states' police powers, such a mandate does not appear to be under consideration. That is, there are many eventualities that would have to occur before a mandate would be ripe for consideration. There was also consensus that absent compelling states through the spending clause (e.g. withholding vaccines), the federal government lacks the power to implement a national vaccine mandate. Although, some

arguments have been made that the federal government could use its' authority pursuant to the Commerce Clause to do so. Indeed, even an incentive program that used vaccine doses as the carrot might quickly run afoul of anti-commandeering law. See *New York v. U.S.,* 505 U.S. 144 (1992). Regardless, such analysis would be highly factually specific and thankfully the emphasis to date remains to encouraging participation in any vaccine program and is not relying upon enforcement or compulsion.

The cohort believes that states retain the authority to not participate in the federal vaccine program if they deemed it necessary. Again, this seems unnecessary at present given that the federal government has paid for vaccines and it is being distributed on a population pro-rata basis equitably without restrictions attached. No cohort participant suggested this was an approach that was attractive given the current state of allocation. If a state was willing to adopt the expenses associated with acting unilaterally, they have the authority to do so. It was noted that any state that chose to act unilaterally might not be able to avoid the federal government entirely because of 1) its exclusive contract with US based vaccine manufacturers and 2) any vaccines procured outside the U.S. would still have to be approved for legal import through traditional means, includes the US FDA. Thus, successful cooperation with the federal government was clearly the most attractive near-term approach.

The cohorts differed in defining the most effective mechanism to incentivize or enforce any emergency health order, including a hypothetical vaccine mandate. While cohort participants generally favored incentives to enforcement though direct monetary payments, it was not endorsed expressly by anyone. The strongest incentive discussed was simply the interest to return to normal; an incentive that could be capitalized during public outreach and advocacy. Other monetary incentives, such as tax credits or health premium deductions were also discussed, though any such steps would require new legislation. Based on states' past attempts at mandatory vaccines, it appears any successful mandate program will require both incentives and penalties. Penalties for non-compliance with past mandatory vaccine health regimes or restricting access to public education because of non-compliance have been deemed lawful and would likely be upheld again. Please see *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) and *Phillips v. City of N.Y.*, 775 F.3d 538 (2nd Cir. 2015). It was discussed by the cohort that the amount of such a penalty, or fine, must be enough to compel compliance, but not be disproportionate to the violation. A penalty deemed too small would not achieve the public policy goal of increasing the number of people willing to be vaccinated. However, as referenced above, the general consensus of the cohort was that if voluntary compliance efforts and incentive programs are not effective from a public health standpoint, states should consider implementing the least restrictive means necessary to promote compliance with vaccine requirements.

Other consequences available for non-compliance were discussed though they become increasingly complex, from a legal perspective. For example, if non-compliance triggered quarantine or loss of ability to work, the analysis of whether such a policy would satisfy rationale basis review is less clear. Mandatory quarantine, for example, is another cognizable power available to authorities under the general emergency statutes. But, it was discussed that

to mandate quarantine for non-sick individuals because they refuse a vaccine could be seen as overreach. Likewise, restricting public movement or restricting someone from pursuing their livelihood would pose a legal quandary. These issues become more complex when the livelihood of the unvaccinated person is also classified as an essential occupation – for example an EMT. It was these challenges, in part, that led the cohort to determine that it was far preferable for states to achieve broad community participation through efforts focused on voluntary compliance, as opposed to mandatory enforcement.

The cohort discussed that an enforcement regime also invites the complexities inherent in the consumer protection approach to vaccines – buying exemptions and constitutional claims. A mandatory vaccination program could still have certain exemptions which might lead to abuse of those exemptions. The cohort did not consider religious exemptions, however, it recognized that religious exemptions to vaccine programs exist and have a long history in the courts. However, currently the Supreme Court has found that states are not required to provide religious exemptions so long as "the law is not specifically directed to religious practice and is otherwise constitutional as applied to those who engage in the specified act for nonreligious reasons." *Oregon v. Smith*, 494 U.S. 872 (1990).

VI. Antitrust Implications Related to Vaccines

Led by Colorado and Nebraska.

Collaboration

The main conclusion of this cohort was that it is still too early to know if there are, or will be, competition concerns related to the manufacture or distribution of COVID-19 vaccines. The other conclusion was that the rules enforcers have historically applied when analyzing or challenging anticompetitive behavior are relatively clear and have not changed simply because there is a pandemic. That is, federal enforcers continue to approach antitrust concerns arising during the pandemic using the same analyses and considerations they typically apply to market behavior, and the states largely have followed suit. If a company participating in the COVID-19 vaccine supply/distribution chain has concerns that its planned activities might trigger antitrust enforcement, the U.S. Department of Justice, which has taken the lead with regards to vaccine issues, appears ready to engage with business to provide guidance. For example, the July guidance letter from DOJ regarding certain collaboration proposals that would further the development of COVID-19 treatments lays out established antitrust principles towards enforcement approach and serves as a guide for States in how to approach these issues. Similarly, the DOJ is available to consult with State enforcers if the States detect issues that may warrant further review or investigation.

Although States have yet to know the full scope of potential competition concerns regarding vaccine manufacture or distribution in the short term, there may be issues to watch in the long term. For example, we do not yet know the number of competitive alternatives for the vaccine past the initial inoculation or what consolidation will occur in the future within the manufacturing distribution chain, but these will be issues to watch. Such consolidation or lack of supply chain resiliency could cause prices to rise if the vaccine is no longer offered to consumers or States at no cost. There may be other antitrust liability issues that come to light, including but not limited to restrictive and exclusionary contracting practices or bundling.

It is clear that throughout the pandemic, enforcers have been and will remain active. Moreover, cohort participants did not suggest that the pandemic called for a change in approach to review and enforcement with respect to COVID-19 vaccines.

Resources:

- DOJ-FTC Antitrust Guidelines for Collaborations Among Competitors
- DOJ-FTC Statements of Antitrust Enforcement Policy in Health Care
- DOJ-FTC Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program
- DOJ's Business Review
- FTC's Advisory Opinion