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Legal Issues in COVID-19 Vaccine Development

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SUMMARY

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Legal Issues in COVID-19 Vaccine Development

Private companies, universities, and governmental entities are working to develop a vaccine for coronavirus disease 2019 (COVID-19). Vaccines are biological products regulated under the Public Health Service Act (PHSA) and the Federal Food, Drug, and Cosmetic Act (FD&C Act). New vaccines must generally be licensed by the U.S. Food & Drug Administration (FDA) before they can be marketed and used in the United States. To obtain licensure, the vaccine must be tested in human subjects through clinical trials. The clinical trials inform the dosing schedule and labeling that will be used for the approved vaccine. Sponsors use the data from clinical trials, along with other information, to prepare a biologics license application (BLA) to submit to FDA. FDA approves the BLA if it determines that the vaccine is safe, potent, and pure.

Because the development and review process can be lengthy, the FD&C Act provides several avenues to accelerate this process for pharmaceutical products intended to treat or prevent serious diseases or conditions. FDA may grant fast track product and breakthrough-therapy designation at the sponsor's request for products that are intended to fill an unmet need or improve on existing therapies. Both designations entitle the sponsor to increased communication with FDA regarding the clinical trial design and data collected, as well as rolling review of the BLA. Products may also qualify for accelerated approval based on intermediate or surrogate endpoints likely to predict a clinical benefit. In addition, FDA may designate products for priority review.

In certain emergency situations, FDA may temporarily authorize the use of unapproved products or approved products for unapproved uses through an emergency use authorization (EUA). For FDA to issue an EUA, the Secretary of Health and Human Services (HHS) must determine (1) that a qualifying emergency exists caused by a biological, chemical, radiological, or nuclear (BCRN) agent and (2) that the BCRN agent can cause a serious or life-threatening disease. The Secretary, through FDA, must also determine for each product that (3) it is reasonable to believe, based on the totality of the evidence available, that the product may treat or prevent the disease caused by the BCRN agent and that the known and potential benefits outweigh the known and potential risks, and (4) there are no approved, adequate, and available alternatives. If FDA issues an EUA, the product may be marketed and used for the authorized use while the emergency persists unless FDA revokes the EUA. FDA may also modify or waive good manufacturing practice and prescription requirements when issuing an EUA.

FDA approval of a vaccine allows for its marketing, but does not guarantee that the vaccine will be widely available or affordable. Because patents grant inventors the exclusive rights in a patented invention, patents may influence COVID-19 vaccine affordability and access. Federal agencies and funding support many of the COVID-19 vaccine candidates in development, which may affect the allocation and scope of patent rights. The Bayh-Dole Act allows a federal contractor to obtain the patent on a federally funded invention, but the government retains a free license to use the invention and may "march in" to grant patent licenses to third-party manufacturers in limited circumstances. If federal support is provided through an "other transaction" agreement, however, the allocation of patent rights will depend on the terms of that contract.

The federal government has several authorities that it could exercise should patent rights limit the affordability of or access to a COVID-19 vaccine. For vaccines developed with federal funding or support, the government may secure up-front guarantees on pricing or distribution via funding or purchasing contracts with vaccine developers. For vaccines protected by patents subject to the Bayh-Dole Act, the funding agency could seek to invoke march-in rights to enable other producers to manufacture the vaccine. For any U.S. patent, the federal government could use its "eminent domain" powers under 28 U.S.C. § 1498, which allows the government to make and use patented inventions without license—so long as the use is by or for the United States and compensation is provided to the patent holder. As U.S. patent rights are a creation of Congress, targeted legislation is another option, subject to the constraints of the U.S. Constitution and international treaties.

A COVID-19 vaccine is likely to be subject to specialized rules limiting legal liability under the Public Readiness and Emergency Preparedness (PREP) Act. To encourage the expeditious development and deployment of medical countermeasures, the Secretary of HHS has declared COVID-19 to be a public health emergency and invoked the PREP Act to limit liability for losses relating to the use of covered medical countermeasures during the public health emergency. Under HHS's declaration, covered persons—including COVID-19 vaccine developers, manufacturers, distributors, and health care professionals who administer a vaccine—are generally immune from legal liability for losses relating to administration or use of an FDA-approved COVID-19 vaccine, except for willful misconduct resulting in death or serious physical injury. However, individuals who are injured or die as a result of receiving a COVID-19 vaccine may seek compensation through the Countermeasures Injury Compensation Program, a regulatory process administered by HHS.

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Around the world, private companies, universities, and governmental entities are rapidly working to develop a vaccine for coronavirus disease 2019 (COVID-19).[1] In the United States alone, private industry and universities are developing and testing dozens of COVID-19 vaccine candidates,[2] often in collaboration with federal agencies and/or supported by federal funding. For example, the Biomedical Advanced Research and Development Authority (BARDA) has partnered with Janssen Pharmaceuticals (a Johnson & Johnson subsidiary) and Sanofi to help develop and scale up manufacturing capacity for each company's COVID-19 vaccine candidate.[3] Together with the National Institute of Allergy and Infectious Diseases (NIAID), BARDA is also collaborating with Moderna to support the development of its COVID-19 vaccine candidate.[4]

More generally, the Trump Administration recently announced the creation of a program called Operation Warp Speed, which seeks to use coordinated government support to accelerate the development, manufacturing, and distribution of COVID-19 vaccines and other medical countermeasures.[5] With respect to vaccines, the program initially selected fourteen promising vaccine candidates, which was subsequently narrowed to five candidates.[6] Under Operation Warp Speed, the federal government is investing in scaling up manufacturing and distribution for selected COVID-19 vaccine candidates "at risk" (that is, before safety and efficacy is demonstrated).[7] For example, under the program, BARDA has entered into agreements to accelerate the development and manufacturing of a vaccine candidate being developed by the University of Oxford and AstraZeneca.[8]

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[1] *See Draft Landscape of COVID-19 Candidate Vaccines*, WORLD HEALTH ORGANIZATION (June 2, 2020), https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines (listing 133 COVID-19 vaccine candidates in various stages of development worldwide); Jeff Craven, *COVID-19 Vaccine Tracker*, REG. AFF. PROFS. SOC'Y (June 1, 2020), https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker (tracking COVID-19 vaccine candidates currently in clinical trials).

[2] *See* Tung Thanh Le et al., *The COVID-19 Vaccine Development Landscape*, NATURE REV. DRUG DISCOVERY (Apr. 9, 2020), https://www.nature.com/articles/d41573-020-00073-5 (breaking down COVID-19 vaccine candidates by geographical location of lead developer).

[3] *See* Press Release, U.S. Department of Health and Human Services, HHS, Janssen Join Forces On Coronavirus Vaccine (Feb. 11, 2020), https://www.hhs.gov/about/news/2020/02/11/hhs-janssen-join-forces-on-coronavirus-vaccine.html; Press Release, U.S. Department of Health and Human Services, HHS Engages Sanofi's Recombinant Technology for 2019 Novel Coronavirus Vaccine (Feb. 18, 2020), https://www.hhs.gov/about/news/2020/02/18/hhs-engages-sanofis-recombinant-technology-for-2019-novel-coronavirus-vaccine.html.

[4] *See* Press Release, U.S. Department of Health and Human Services, HHS Accelerates Clinical Trials, Prepares for Manufacturing of COVID-19 Vaccines (Mar. 30, 2020).

[5] *See* Press Release, U.S. Department of Health and Human Services, Trump Administration Announces Framework and Leadership for "Operation Warp Speed" (May 15, 2020), https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html.

[6] *See* Noah Weiland & David E. Sanger, *Trump Administration Selects Five Coronavirus Vaccine Candidates as Finalists*, N.Y. TIMES (June 3, 2020), https://www.nytimes.com/2020/06/03/us/politics/coronavirus-vaccine-trump-moderna.html. The five candidates are vaccines being developed by (1) Moderna/NIAID; (2) University of Oxford/AstraZeneca; (3) Johnson & Johnson; (4) Merck; and (5) Pfizer/BioNTech. *See id.*

[7] *See* Jennifer Jacobs and Drew Armstrong, *Trump's 'Operation Warp Speed' Aims to Rush Coronavirus Vaccine*, BLOOMBERG (Apr. 29, 2020), https://www.bloomberg.com/news/articles/2020-04-29/trump-s-operation-warp-speed-aims-to-rush-coronavirus-vaccine.

[8] Press Release, U.S. Department of Health and Human Services, Trump Administration's Operation Warp Speed Accelerates AstraZeneca COVID-19 Vaccine to be Available Beginning in October (May 21, 2020), https://www.hhs.gov/about/news/2020/05/21/trump-administration-accelerates-astrazeneca-covid-19-vaccine-to-be-available-beginning-in-october.html.

This report overviews certain legal issues in COVID-19 vaccine development, testing, licensing, production, and administration, focusing on three areas: (1) vaccine testing, authorization, and licensure by the U.S. Food and Drug Administration (FDA); (2) patent and other intellectual property (IP) rights that may protect a COVID-19 vaccine; and (3) liability and compensation issues for individuals harmed by the testing or administration of a vaccine.

First, this report explains the existing legal requirements for clinical trials and FDA authorization or licensure of new vaccines, including different options to accelerate those processes. Second, it analyzes who might own the patent rights in a potential COVID-19 vaccine, and the federal government's legal options should patent rights restrict the affordability or availability of a vaccine. Third, it reviews the protections from legal liability available to vaccine developers, manufacturers, administrators, and healthcare professionals under the Public Readiness and Emergency Preparedness (PREP) Act.

FDA Law Considerations: Bringing a New Vaccine to Market

Vaccines are intended to prevent diseases and generally work by introducing pathogens to the human body (usually by injection) to trigger an immune response to the disease (i.e., producing antibodies to the pathogen).[9] Vaccines are biological products approved and regulated by FDA's Center for Biologics Evaluation and Research (CBER) under Section 351 of the Public Health Service Act (PHSA).[10] A biologic such as a vaccine generally cannot be introduced into commerce unless FDA approves it.[11] To be approved, FDA must determine that the vaccine is safe, potent, and pure based on data from laboratory studies and clinical trials.[12] This section discusses the legal framework for developing, testing, and licensing (i.e., approving) new vaccines under the PHSA and the Federal Food, Drug, and Cosmetic Act (FD&C Act), as well as existing legal avenues that would allow that process to be expedited to bring a new vaccine to market sooner.

Clinical Trials of Investigational New Drugs

Sponsors use clinical trials to generate the data needed to obtain FDA approval to market their products. Because clinical trials expose human subjects to unapproved pharmaceutical products, they risk causing unanticipated serious adverse side effects in the participants. To manage these risks, the FD&C Act and FDA regulations have imposed procedural requirements, such as advance and ongoing scientific and ethical review, on clinical trials to help protect the participants by minimizing risks, requiring informed consent, and ensuring that the studies collect the data needed to determine whether to approve the product.

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[9] *Vaccines: The Basics*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/vpd/vpd-vac-basics.html (last updated Mar. 14, 2012); *Understanding How Vaccines Work*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/hcp/conversations/understanding-vacc-work.html (last updated Aug. 17, 2018).

[10] 42 U.S.C. § 262; *Vaccine Product Approval Process*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process (last updated Jan. 30, 2018) [hereinafter *FDA Vaccine Approval Process*].

[11] 42 U.S.C. § 262(a)(1).

[12] *Id.* § 262(a)(2); 21 C.F.R. § 601.2.

Using Clinical Trials to Collect Substantial Evidence

Sponsors must submit "substantial evidence" to FDA that their products are safe and effective (or safe, potent, and pure) to obtain FDA approval.[13] Section 505(d) of the FD&C Act defines substantial evidence to mean adequately and well-controlled investigations on the basis of which qualified scientific experts could fairly and responsibly conclude that the product has the purported effect.[14] FDA assesses both the quality and quantity of the data provided when determining whether a product meets this standard.[15]

Quality refers to the strength of the evidence and the amount of certainty it provides as to the product's safety and effectiveness—that is, whether the investigation is "adequate" and "well-controlled."[16] The quality of the evidence depends on how the clinical trial is designed and how the study is conducted.[17] Under FDA regulations, the design must allow for a valid comparison of the product to a control, such as a placebo, an existing therapy, or no treatment.[18] FDA also evaluates whether the study's method for selecting participants and assigning them to groups is adequate to ensure that meaningful data are collected.[19] The methodology must also include a well-defined and reliable means of assessing the participants' responses and explain the analytical and statistical methods used to assess the results.[20] Finally, sponsors must provide a clear statement of the investigation's objectives and take adequate measures to minimize bias in the study.[21] FDA may, however, waive any of these criteria for a specific investigation if the sponsor can show that the criteria are not reasonably applicable to the study and an alternative approach yields substantial evidence of effectiveness.[22] FDA guidance further clarifies how sponsors should select their clinical trial design, endpoints, and statistical methods.[23]

As for quantity, FDA generally requires that sponsors complete two "adequate and well-controlled clinical investigations" to meet the substantial evidence standard.[24] FDA notes in its guidance that completing two studies, particularly if they are designed and conducted differently, reduces the likelihood of a design flaw, bias, or other issue or anomaly that could result in erroneous conclusions.[25] However, under the Food and Drug Modernization Act of 1997,[26] FDA may allow sponsors to rely on one large multicenter adequate and well-controlled clinical investigation supported by another form of additional data,[27] such as data regarding the

[13] 21 U.S.C. § 355(d).

[14] *Id.*

[15] U.S. FOOD & DRUG ADMIN., DEMONSTRATING SUBSTANTIAL EVIDENCE OF EFFECTIVENESS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS: DRAFT GUIDANCE FOR INDUSTRY 3 (Dec. 2019), https://www.fda.gov/media/133660/download [hereinafter DEMONSTRATING SUBSTANTIAL EVIDENCE.[16] *Id.* at 5.

[16] *Id.* at 5.

[17] 21 C.F.R. § 314.126.

[18] *Id.* § 314.126(b)(2).

[19] *Id.* § 314.126(b)(3) & (4).

[20] *Id.* § 314.126(b)(6) & (7).

[21] *Id.* § 314.126(b)(1) & (5).

[22] *Id.* § 314.126(c).

[23] DEMONSTRATING SUBSTANTIAL EVIDENCE, *supra* note 15, at 5.

[24] *Id.* at 8.

[25] *Id.* at 9-10.

[26] Pub. L. No. 105-115 § 115, 111 Stat. 2313 (1997).

[27] 21 U.S.C. § 355(d).

effectiveness of other drugs in the same pharmacological class.[28] In deciding whether to allow a sponsor to rely on a single study, FDA states that it considers, among other factors, the seriousness of the disease, whether there is an unmet medical need, and whether additional trials would be ethical and practicable.[29]

Given the flexibility afforded sponsors in designing and conducting their clinical trials, FDA uses written guidance and individual meetings to help sponsors ensure that their investigations will generate the substantial evidence needed for approval.[30] Sponsors that obtain fast track product or breakthrough therapy designation for their products are entitled to additional assistance from and communication with FDA staff to craft efficient and effective clinical trial designs.[31]

Submitting an Investigational New Drug Application to FDA

New drugs and biological products that are being tested in clinical trials are referred to as investigational new drugs.[32] Section 505(i) of the FD&C Act, Section 351(a)(3) of the PHSA, and their implementing regulations allow investigational new drugs to be used for research before they are approved.[33] To conduct clinical trials of investigational new drugs, the company developing the product (i.e., sponsor) must generally receive FDA approval for the investigation and comply with regulatory requirements for human subjects research.[34]

Sponsors obtain FDA approval to test an investigational new drug on human subjects through an investigational new drug application (IND).[35] The IND gives FDA an opportunity to ensure that the study will protect the safety and rights of its human subjects and gather scientific data that adequately show the product's safety and effectiveness.[36] The sponsor may begin its clinical trials 30 days after submitting an IND unless FDA notifies the sponsor that it is either (1) authorizing the IND and the study can begin immediately or (2) imposing a clinical hold due to concerns about the study.[37] If FDA imposes a clinical hold, the study cannot begin (or resume, for ongoing investigations) pending further notification.[38]

FDA regulations prescribe the information that sponsors must include in an IND.[39] The IND must contain information about the product, such as the substance and formulation; existing data on use in animals or humans if available; and anticipated risks and side effects.[40] The IND must also contain a general investigational plan, which explains why the sponsor is undertaking the study and includes, among other things, the indications being studied, the sponsor's approach to evaluating the product, the kinds of clinical trials being conducted, the anticipated number of

[28] DEMONSTRATING SUBSTANTIAL EVIDENCE, *supra* note 15, at 12.

[29] *Id.* at 10.

[30] *See, e.g.*, 21 C.F.R. § 312.47; DEMONSTRATING SUBSTANTIAL EVIDENCE, *supra* note 15.

[31] *See* "Shortening the Development and Review Processes."

[32] 21 C.F.R. § 312.3.

[33] 21 U.S.C. § 355(i); 42 U.S.C. § 262(a)(3); 21 C.F.R. § 312.2(a).

[34] *See generally* 21 C.F.R. Parts 50, 56, & 312.

[35] 21 C.F.R. § 312.20; *Investigational New Drug (IND) Application*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application (last updated May 12, 2020).

[36] 21 C.F.R. § 312.22.

[37] *Id.* §§ 312.40 & 312.42.

[38] *Id.* § 312.42(a) & (e).

[39] *Id.* § 312.23.

[40] *Id.*

participants, and any anticipated risks.[41] Along with the general investigational plan, the IND must include specific protocols for each clinical trial phase.[42] The sponsor must also generally certify that an institutional review board (IRB) will provide initial and continuing review of each study, including the proposed protocols and any subsequent changes to the study.[43] FDA may, however, waive any IRB requirements, including the requirement of IRB review itself.[44]

Institutional Review Board Review and Approval

An IRB is a group convened by an institution to review and approve biomedical research involving humans.[45] IRBs evaluate the initial clinical study design and protocols, along with any changes implemented during the investigation, in an effort to ensure that the rights and well-being of the human subjects are protected.[46] To that end, IRBs assess whether risks to the participants are minimized and reasonable in relation to the anticipated benefits, both to the participants directly and from the knowledge expected to be gained through the study.[47] IRBs also aim to ensure that the researchers will obtain adequate informed consent from all participants (unless an exemption applies) and that selection of the participants will be equitable.[48] IRBs may also require (as appropriate) that the research plan provide for monitoring of the collected data to protect the participants' safety and privacy.[49] To the extent the study may include participants from populations that may be vulnerable to coercion or undue influence (e.g., children, prisoners), IRBs must ensure that sufficient safeguards are in place to protect these populations in participant selection and during the clinical trials.[50]

IRBs review clinical trial plans and protocols from various standpoints, including ensuring that the study complies with legal, ethical, and professional standards; is scientifically sound; and is free from illicit discrimination. Accordingly, to ensure adequate and independent review, IRBs must have at least five members from multiple backgrounds, including at least one member with a scientific background and at least one with a nonscientific background.[51] At least one member must be independent from the institution running the clinical trials, and the IRB members cannot have any financial or other conflicting interests in the project.[52] IRB review must comply with any other requirements relating to IRBs and human subject research found in Parts 50 and 56 of Chapter 21 of the Code of Federal Regulation.

Clinical Trial Phases

Clinical trials for a new pharmaceutical product generally proceed in three phases, transitioning from smaller trials focused on initial safety early on to larger trials assessing safety and

[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] 21 C.F.R. § 56.105(c).
[45] *Id.* § 56.102(g).
[46] *Id.*
[47] *Id.* § 56.111(a)(1)-(2).
[48] *Id.* § 56.111(a)(3)-(5).
[49] *Id.* § 56.111(a)(6)-(7).
[50] *Id.* § 56.111(b) & (c).
[51] *Id.* § 56.107(a)-(c).
[52] *Id.* § 56.107(d)-(e).

effectiveness to inform approval and labeling.[53] The size, duration, and specific purpose of each clinical trial phase varies from product to product depending on such factors as the type of product (e.g., a vaccine, treatment, or preventative medication), how the product works, and the relevant underlying patient population. However, as defined by FDA regulations, a clinical investigation generally proceeds as follows:

- **Phase 1 Trials.** Phase 1 trials are the first time the product is introduced in human subjects.[54] These carefully controlled trials typically involve 20 to 80 patients or volunteer subjects, though the exact numbers may vary depending on the product.[55] Phase 1 trials generally assess how the product acts in the body and evaluate initial safety (i.e., side effects).[56] They may also be used to determine the dosing levels to use in phase 2 (e.g., the maximum safe dose or what dose is required to have an effect).[57] Depending on the product, phase 1 trials may also provide some initial indication as to whether the product may be effective.[58] In the case of vaccines specifically, phase 1 trials also assess their ability to provoke an immune response in the body (i.e., immunogenicity).[59]
- **Phase 2 Trials.** Phase 2 trials continue to assess safety but also evaluate the product's effectiveness and common short-term side effects or other risks associated with the product.[60] Phase 2 trials are also used to determine the optimal dose of the product.[61] For vaccines, phase 2 assesses how much of the vaccine to administer and on what dosing schedule (e.g., whether a boost is needed to maximize its effectiveness or whether the vaccine must be administered on a regular schedule to maintain immunity).[62] As with phase 1 studies, phase 2 studies are carefully controlled.[63] However, phase 2 involves a larger (though still relatively limited) number of volunteer subjects—generally no more than a few hundred participants.[64]
- **Phase 3 Trials.** Phase 3 trials involve an expanded number of participants—from several hundred to thousands—and are used to assess the product's safety and effectiveness across a wide range of patient categories through controlled and uncontrolled studies.[65] These trials are intended to present a clearer picture of

[53] *Id.* § 312.21.

[54] *Id.* § 312.21(a).

[55] *Id.*

[56] *Id.*

[57] *Id.*

[58] *Id.*

[59] *FDA Vaccine Approval Process*, *supra* note 10.

[60] 21 C.F.R. § 312.21(b).

[61] *See, e.g.*, Kert Viele & Jason T. Connor, *Dose Finding Trials: Optimizing Phase 2 Data in the Drug Development Process*, 314 J. AM. MED. ASS'N 2294, 2294 (2015), https://jamanetwork.com/journals/jama/fullarticle/2473474.

[62] *FDA Vaccine Approval Process*, *supra* note 10.

[63] 21 C.F.R. § 312.21(b).

[64] *Id.*

[65] *Id.* § 312.21(c).

expected risks and benefits under real-world conditions.[66] The information obtained from phase 3 trials also forms the basis for the product's labeling.[67]

Sponsors must generally complete all three phases to obtain FDA approval unless they obtain accelerated approval,[68] in which case FDA requires postapproval trials to confirm the expected clinical benefit.[69] FDA may also require, at its discretion, additional clinical trials after approval (i.e., phase 4 trials) for any approved product to continue assessing the product's safety and effectiveness once on the market.[70]

Considerations for Congress

The current legal framework seeks to balance various competing interests, which may be amplified in the current crisis. The FD&C Act and implementing regulations provide standards and factors to consider but otherwise give FDA and IRBs discretion to evaluate investigational plans and clinical trial protocols for investigational new drugs. FDA may also waive requirements relating to IRB review and clinical trial design. To the extent Congress may seek to direct how FDA and IRBs exercise that discretion with respect to any potential COVID-19 vaccine, Congress could consider implementing legislation that provides more specific direction on how to approach clinical trials either specifically for the current COVID-19 pandemic or in epidemic, pandemic, or other emergency situations more generally. For example, courts have determined that Congress can cabin FDA's discretion by imposing mandatory (e.g., "shall") rather than permissive (e.g., "may") language in a statute.[71]

In light of the multiple companies involved in developing potential COVID-19 vaccines, Congress could also consider facilitating the coordination of any clinical trials or appointing a neutral scientific body to consider the ethical and scientific considerations and generate guidelines or a master protocol. The World Health Organization (WHO) employed this approach to facilitate development of an Ebola vaccine following the 2014 to 2016 Ebola epidemic.[72] Congress could also direct or fund increased global collaboration between regulators to promote information sharing, which could potentially result in more streamlined clinical investigations with fewer participants being exposed to investigational vaccines.[73] Congress could also consider providing additional funding or other resources to facilitate the clinical trials themselves or any research directed toward understanding the SARS-CoV-2 virus or COVID-19 disease to allow for improved risk minimization in future clinical trials.

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[66] *Id.*

[67] *Id.*

[68] *Accelerated Approval*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval (last updated Jan. 4, 2018).

[69] DEMONSTRATING SUBSTANTIAL EVIDENCE, *supra* note 15, at 2.

[70] 21 C.F.R. § 312.85.

[71] *See, e.g.*, Cook v. FDA, 733 F.3d 1, 8 (D.C. Cir. 2013).

[72] WORLD HEALTH ORG., WHO R&D BLUEPRINT – AD-HOC WORKSHOP ON EBOLA VACCINES: DELIBERATIONS ON DESIGN OPTIONS FOR CLINICAL TRIALS TO ASSESS THE SAFETY AND EFFICACY OF INVESTIGATIONAL EBOLA VACCINES (Jan. 23, 2019), https://www.who.int/docs/default-source/blue-print/ebola-vaccine-meeting-report.pdf?sfvrsn=9dd492f4_2.

[73] *See, e.g.*, *Summary of FDA & EMA Global Regulators Meeting on Data Requirements Supporting First-in-Human Clinical Trials with SARS-CoV-2 Vaccines*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/summary-fda-ema-global-regulators-meeting-data-requirements-supporting-first-human-clinical-trials (last updated Mar. 18, 2020).

FDA Approval and Options for Bringing a New Vaccine to Market Faster

If the clinical trials are successful, the sponsor may seek FDA approval to market its new vaccine. FDA approves new vaccines through biologics license applications (BLAs) reviewed by CBER.[74] BLAs contain data from the laboratory and clinical studies and information about how and where the biologic will be manufactured.[75] As courts have recognized, FDA exercises its scientific judgment when deciding whether to license vaccines based on such studies.[76] Biologics that are approved through a BLA receive 12 years of regulatory exclusivity, during which time FDA cannot approve any biosimilars (i.e., abbreviated applications for the same biologic that depend on the clinical data in the BLA to demonstrate safety, potency, and purity).[77]

The process of developing and testing a new vaccine to the point where it meets the safety, purity, and potency standard can be a lengthy process. The FD&C Act provides several options that may allow a sponsor to bring a new vaccine to market faster.[78] Generally, these options use one of two approaches. First, FDA can direct more of its resources to the product to accelerate the development and/or review processes (e.g., fast track product designation, breakthrough therapy designation, and priority review). Second, FDA can modify how it evaluates the risks and benefits of the vaccine before allowing its use, either by relying on different types of evidence (e.g., the accelerated approval process) or lowering the evidentiary standard in emergency situations (e.g., emergency use authorization). (For ease of reference, this section uses the general term "biologic" because vaccines are biological products, but the pathways discussed below are also available for traditional small molecule drugs.)

Shortening the Development and Review Processes

Several avenues are available for expediting the development and review processes for biologics used to treat or prevent serious or life-threatening conditions and diseases. In its guidance, FDA generally considers a condition or disease *serious* if it substantially affects day-to-day functioning and is irreversible, persistent, or recurrent.[79] A condition or disease may be found to be serious as a matter of clinical judgment based on its effect on survival, day-to-day functioning, or the likelihood that it will progress to a more serious condition if left untreated.[80] As a matter of course, FDA considers any life-threatening condition or disease to be serious.[81] The drug must also be intended to *treat* the serious condition or disease by having an effect on the disease itself or a serious aspect of the disease, such as a symptom or other manifestation.[82] Among the

[74] 21 U.S.C. § 262(a); *FDA Vaccine Approval Process*, *supra* note 10. For additional information about the biologics licensing process, see CRS Report R45666, *Drug Pricing and Intellectual Property Law: A Legal Overview for the 116th Congress*, coordinated by Kevin J. Hickey, at 17-27.

[75] 21 C.F.R. § 601.2.

[76] Rempfer v. Sharfstein, 583 F.3d 860, 868 (D.C. Cir. 2009).

[77] 21 U.S.C. § 262(k)(7)(A).

[78] *See generally* 21 U.S.C. § 356.

[79] U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS – DRUGS AND BIOLOGICS 2-3 (2014), https://www.fda.gov/media/86377/download [hereinafter EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS: FDA GUIDANCE].

[80] 21 C.F.R. § 312.300(b)(1).

[81] EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS: FDA GUIDANCE, *supra* note 79, at 3.

[82] *Id.*

examples FDA provides in its guidance is a product intended to *prevent* the serious condition.[83] Given that COVID-19 is life threatening, a vaccine intended to prevent COVID-19 seems likely to qualify as a drug used to treat or prevent a serious or life-threatening condition or disease—making it eligible for the following designations to accelerate the approval process.

Fast Track Product Designation

Section 506 of the FD&C Act allows FDA to designate certain biologics as fast track products, which receive FDA assistance in expediting development and review.[84] A biologic may be designated as a fast track product if FDA determines that the biologic will treat or prevent a serious or life-threatening disease or condition and fill an unmet medical need.[85] An unmet medical need exists when available therapies do not adequately address treating or diagnosing a condition or disease.[86] FDA recognizes in its guidance that an unmet medical need necessarily exists if there is no available therapy.[87] Sponsors may provide FDA with nonclinical or clinical data to demonstrate that the drug has the potential to fill that unmet medical need.[88] Given that there are no approved vaccines for COVID-19, any vaccine that showed potential to prevent COVID-19 in laboratory or clinical trials would seem likely to qualify for fast track designation. On May 12, 2020, FDA designated Moderna's COVID-19 vaccine as a fast track product after it completed its Phase 1 trials.[89]

At its discretion, the biologic's sponsor requests fast track designation for its product.[90] It may request fast track designation when it submits an IND or any time thereafter.[91] FDA has 60 days to determine if the biologic qualifies for the designation.[92] Once FDA designates a biologic as a fast track product, FDA must facilitate its development and expedite review of the biologic.[93] In practice, this process generally means that the biologic's sponsor has greater access to FDA through written and in-person communications during the development and testing process to improve efficiency and ensure that appropriate data are collected.[94] FDA may also review the BLA for a fast track product on a rolling basis as sections are complete (rather than waiting for a completed application) if initial clinical testing shows the biologic may be effective.[95]

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[83] *Id.*

[84] 21 U.S.C. § 356(b).

[85] *Id.*

[86] EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS: FDA GUIDANCE, *supra* note 79, at 4.

[87] *Id.* at 5.

[88] *Id.* at 9.

[89] Press Release, Moderna, Moderna Receives FDA Fast Track Designation for mRNA Vaccine (mRNA-1273) Against Novel Coronavirus (May 12, 2020), https://investors.modernatx.com/news-releases/news-release-details/moderna-receives-fda-fast-track-designation-mrna-vaccine-mrna.

[90] 21 U.S.C. § 356(b)(2).

[91] *Id.*

[92] *Id.* § 356(b)(3).

[93] *Id.*

[94] EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS: FDA GUIDANCE, *supra* note 79, at 9; *Fast Track*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track (last updated Jan. 4, 2018).

[95] EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS: FDA GUIDANCE, *supra* note 79, at 10; U.S. Food & Drug Admin., Fast Track (Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.

Breakthrough Therapy Designation

Section 506 of the FD&C Act also allows FDA to designate certain biologics as breakthrough therapies, which similarly heightens FDA involvement in the development and review process.[96] Breakthrough therapy designation is based on preliminary clinical evidence showing the biologic may be a substantial improvement over available therapies for one or more clinically significant endpoints.[97] Endpoints measure the outcome of a clinical trial.[98] Under FDA guidance, a clinically significant endpoint generally measures an effect on irreversible morbidity or mortality or on symptoms representing serious consequences of the disease or condition.[99] Unlike fast track product designation, which can be based on laboratory data, breakthrough therapy designation requires evidence from clinical trials.[100] FDA exercises its judgment in determining whether the data show a substantial improvement over existing therapies, taking into consideration both the magnitude of the biologic's effects on the endpoint and the importance of the effect measured by that endpoint to treating the disease or condition.[101] When there are no existing therapies, such as with a COVID-19 vaccine, FDA compares the biologic to a placebo or well-documented historical control.[102] A COVID-19 vaccine may be eligible for breakthrough therapy designation if the sponsor can demonstrate potential effectiveness in early clinical trials.

At its discretion, the sponsor requests breakthrough therapy designation and may do so with submission of an IND or at any time thereafter.[103] FDA must determine whether the biologic qualifies as a breakthrough therapy within 60 days of receipt.[104] As with fast track product designation, the FD&C Act directs FDA to expedite the development and review of applications for breakthrough therapies.[105] Per FDA guidance, expedited development and review of breakthrough therapies entails (1) intensive assistance from FDA on efficient development and clinical trial design; (2) organizational commitment from FDA, including senior management and experienced staff; (3) rolling review of the BLA; and (4) other actions to expedite review, such as priority review discussed below.[106] Extensive FDA assistance during the development process and the involvement of senior managers distinguishes breakthrough therapy designation from fast track product designation.

Accelerated Approval

Section 506 of the FD&C Act also allows FDA to approve certain biologics based on surrogate or intermediate endpoints, referred to as accelerated approval.[107] In general, sponsors select

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[96] 21 U.S.C. § 356(a).

[97] *Id.* § 356(a)(1).

[98] *Surrogate Endpoint Resources for Drug and Biologic Development*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/development-resources/surrogate-endpoint-resources-drug-and-biologic-development (la updated July 24, 2018).

[99] EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS: FDA GUIDANCE, *supra* note 79, at 12.

[100] *Id.* at 11-12; *compare* 21 U.S.C. § 356(a)(1), *with id.* § 356(b)(1).

[101] EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS, *supra* note 79, at 12.

[102] *Id.*

[103] 21 U.S.C. § 356(a)(2).

[104] *Id.* § 356(a)(3)(A).

[105] *Id.* § 356(a)(3)(B).

[106] EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS: FDA GUIDANCE, *supra* note 79, at 13-15.

[107] 21 U.S.C. § 356(c); *see also Accelerated Approval*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval (updated Jan. 4, 2018).

endpoints that directly measure the clinical outcome (i.e., the benefits expected from the biologic), such as whether the patient feels better or lives longer.[108] Surrogate and intermediate endpoints do not measure the clinical benefit directly but instead measure an effect that is expected to predict a clinical benefit.[109] For example, a drug to treat strokes would have an intended clinical outcome of reducing the incidence or severity of strokes.[110] But rather than measuring the incidence of strokes directly, an investigator might measure the drug's effect on blood pressure as a surrogate endpoint due to the strong correlation between strokes and blood pressure.[111]

To qualify for accelerated approval, (1) the biologic must treat a serious or life-threatening condition or disease and (2) FDA must determine that the biologic has an effect on a surrogate or intermediate endpoint that is reasonably likely to predict a clinical benefit. When deciding whether to approve a biologic on this basis, FDA must consider how severe, rare, or prevalent the condition is and the availability of alternative treatments. A vaccine for COVID-19 could qualify for accelerated approval if investigators identified a surrogate or intermediate endpoint that could reasonably predict the vaccine would be effective against the virus.

Priority Review

Once a BLA is submitted, FDA can designate the BLA for standard review or priority review.[112] FDA aims to act on priority review applications within 6 months, compared to 10 months or more for standard review applications.[113] FDA makes this determination for every application, though a sponsor can expressly request priority review.[114] FDA may designate a BLA for priority review if it represents a "significant improvement" over existing treatments in terms of safety or effectiveness in treating, diagnosing, or preventing the disease or condition.[115] In the absence of any approved vaccine for COVID-19, FDA would likely designate for priority review any BLA for such a vaccine.

Emergency Use Authorizations Before Approval

In certain emergency situations, Section 564 of the FD&C Act allows FDA to authorize the use of a drug or biologic (e.g., a vaccine) before it is approved (i.e., an Emergency Use Authorization or EUA).[116] FDA may issue an EUA only if the Secretary of Health and Human Services (HHS) has

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[108] *See Surrogate Endpoint Resources for Drug and Biologic Development*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/development-resources/surrogate-endpoint-resources-drug-and-biologic-development (last updated July 24, 2018).

[109] *Id*.

[110] *Id*.

[111] *Id*.

[112] Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (1992); *Priority Review*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review. (last updated Jan. 4, 2018) [hereinafter *Priority Review*].

[113] *Priority Review*, *supra* note 112; EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS: FDA GUIDANCE, *supra* note 79, at 24-25.

[114] *Priority Review*, *supra* note 112.

[115] *Priority Review*, *supra* note 112; EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS: FDA GUIDANCE, *supra* note 79, at 24-25.

[116] 21 U.S.C. § 360bbb-3; *see also Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov (last updated May 22, 2020).

declared that circumstances exist justifying emergency authorized use of the medical product.[117] Of relevance to the COVID-19 pandemic, on February 4, 2020, the Secretary determined that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent (BCRN agent)—namely, the virus that causes COVID-19.[118] Based on this determination, the Secretary has authorized the emergency use of several diagnostic tests.[119] On March 2, 2020, the Secretary determined that circumstances exist to allow for the emergency use of certain respirators not approved by the agency,[120] and FDA issued an EUA allowing for the emergency use of such respirators.[121]

After the Secretary determines a public health emergency exists (one of four bases for declaring an emergency or threat), FDA may issue an EUA for a specific product if the Secretary concludes that

1. the BCRN agent can cause a serious or life-threatening disease or condition;
2. it is reasonable to believe, based on the totality of the scientific evidence available, that
    a. the product may be effective in diagnosing, treating, or preventing the disease or condition caused by the BCRN agent; and
    b. the known and potential benefits of the product outweigh the known and potential risks; and
3. there is no adequate, approved, and available alternative to the product.[122]

In evaluating a product for an EUA, FDA uses a lower evidentiary standard, determining whether the product "may be effective" in diagnosing, treating, or preventing a disease rather than evaluating its "effectiveness" in doing so.[123] As discussed above, COVID-19 is a serious or life-threatening disease, confirmed by the fact that FDA has already issued EUAs in connection with COVID-19 for diagnostic tests and certain personal protective equipment.[124] There is also no alternative to a COVID-19 vaccine at this time.[125] Any decision by FDA to issue an EUA for a

[117] *See* 21 U.S.C. § 360bbb-3(b).

[118] Alex M. Azar II, Sec'y of the Dep't of Health & Human Servs., Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3 (Feb. 4, 2020), https://www.fda.gov/media/135010/download.

[119] *See Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov (last updated May 22, 2020).

[120] Alex M. Azar II, Sec'y of the Dep't of Health & Human Servs., Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3 (Mar. 2, 2020), https://www.fda.gov/media/135787/download.

[121] Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Dr. Redfield, Director, Ctrs. for Disease Control & Prevention (Mar. 28, 2020), https://www.fda.gov/media/135763/download.

[122] 21 U.S.C. § 360bbb-3(c).

[123] U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS AND RELATED AUTHORITIES: GUIDANCE FOR INDUSTRY AND OTHER STAKEHOLDERS 12 (Jan. 2017), https://www.fda.gov/media/97321/download.

[124] *Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov (last updated May 22, 2020).

[125] Press Release, Nat'l Insts. of Health, NIH Clinical Trial of Investigational Vaccine for COVID-19 Begins (Mar. 16, 2020), https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins; *WHO Draft Landscape of COVID-19 Candidate Vaccines*, *supra* note 1.

COVID-19 vaccine would accordingly depend on whether the totality of the evidence available to FDA shows that it is reasonable to believe that (1) the vaccine may be effective in preventing COVID-19 and (2) those benefits outweigh any known or potential risks from the vaccine. FDA would have to conduct this evaluation for each vaccine that is developed and submitted for an EUA.

The FD&C Act requires FDA to impose certain conditions on EUAs as necessary and appropriate to protect the public health.[126] The conditions vary depending on whether the product is unapproved or approved but for a different use.[127] In general, the conditions provide for monitoring, reporting, and recordkeeping as well as ensuring that the health care professionals administering the product and the individuals being treated with the product are informed about the benefits and risks of using the product.[128] FDA may also waive good manufacturing practices (GMP) and certain prescription requirements when issuing an EUA and may impose conditions related to advertising the product.[129]

Considerations for Congress

The current legal regime for approving new pharmaceutical products such as vaccines generally aims to strike a balance between bringing products to market sooner and ensuring that products on the market are safe and effective. For serious or life-threatening diseases and conditions or in emergency situations, the law gives FDA a certain amount of discretion to shift that balance. FDA generally expedites the process one of two ways: shifting its resources or shifting its standard in evaluating the risks and benefits.

In considering avenues to facilitate the development of a COVID-19 vaccine, Congress has similar options. Congress could consider providing additional resources to FDA to exercise its existing authorities. Congress is already employing this approach: The Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, enacted on March 6, appropriated $61 million to FDA "to prevent, prepare for, and respond to coronavirus, domestically or internationally, *including the development of necessary medical countermeasures and vaccines*, advanced manufacturing for medical products, the monitoring of medical product supply chains, and related administrative activities."[130] Alternatively, Congress could direct FDA to strike a different balance when evaluating the risks versus the benefits specifically in the context of potential COVID-19 vaccines. In assessing that balance, Congress and FDA would face weighing the benefits from disseminating a vaccine to the public sooner (e.g., limiting the spread of the virus or reducing the economic consequences) against the risk that the vaccine may have been authorized prematurely and prove ineffective or unsafe, potentially leading to worse public health outcomes. Any alteration to this balance that requires FDA to exceed or contradict its existing authority would require an act of Congress to amend the agency's statutory authority.

Should FDA authorize or approve a COVID-19 vaccine, other considerations may come to bear. For example, registered manufacturers may not be able to produce an adequate supply of the vaccine. FDA is currently addressing hand sanitizer shortages by exercising its enforcement discretion with respect to production by over-the-counter drug manufacturers and

[126] 21 U.S.C. § 360bbb-3(e).

[127] *Id*. § 360bbb-3(e)(1) & (2).

[128] *Id*.

[129] Id. § 360bbb-3(e)(3) & (4).

[130] Pub. L. No. 116-123, 134 Stat. 146 (2020) (emphasis added).

compounders.[131] Congress may consider other avenues for increasing supply of the vaccine. In addition, existence of a vaccine would raise questions of mandatory vaccination to address the public health crisis, which is addressed in a CRS Legal Sidebar.[132]

Patent Rights in COVID-19 Vaccines: Incentives, Access, and Affordability

FDA authorization or licensure of a COVID-19 vaccine would permit the manufacturer to market the vaccine, but does not guarantee that the vaccine will be widely available or affordable. A significant factor that may influence COVID-19 vaccine affordability and access is the existence and allocation of IP rights in a vaccine, such as patent rights.[133] If some element of a successful COVID-19 vaccine was patented, for example, the patent holder would have the exclusive right to make and use that COVID-19 vaccine within the United States.[134]

Some Members of Congress have raised concerns about whether a COVID-19 vaccine and other medical countermeasures, if shown to be safe and effective, will be affordable and accessible to the public—especially if federal funds contribute to their development.[135] Several of the congressional responses to the COVID-19 pandemic contain provisions that relate to this issue. First, under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, most private health insurance plans must cover a COVID-19 vaccine and other COVID-19 preventative services without cost sharing (e.g., deductibles or co-pays).[136] Although this provision aims to

[131] Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Provides Guidance on Production of Alcohol-Based Hand Sanitizer to Help Boost Supply, Protect Public Health (Mar. 20, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-guidance-production-alcohol-based-hand-sanitizer-help-boost; U.S. FOOD & DRUG ADMIN., TEMPORARY POLICY FOR PREPARATION OF CERTAIN ALCOHOL-BASED HAND SANITIZER PRODUCTS DURING THE PUBLIC HEALTH EMERGENCY (COVID-19): GUIDANCE FOR INDUSTRY, https://www.fda.gov/media/136289/download (updated June 1, 2020); U.S. FOOD & DRUG ADMIN., POLICY FOR TEMPORARY COMPOUNDING OF CERTAIN ALCOHOL-BASED HAND SANITIZER PRODUCTS DURING THE PUBLIC HEALTH EMERGENCY: IMMEDIATELY IN EFFECT GUIDANCE FOR INDUSTRY https://www.fda.gov/media/136118/download (updated June 1, 2020).

[132] CRS Legal Sidebar LSB10300, *An Overview of State and Federal Authority to Impose Vaccination Requirements*, by Wen S. Shen.

[133] *See, e.g.*, Médecins Sans Frontières/Doctors Without Borders, *MSF Calls for No Patents or Profiteering on COVID-19 Drugs, Tests, and Vaccines in Pandemic*, MSF ACCESS CAMPAIGN (Mar. 27, 2020), https://msfaccess.org/msf-calls-no-patents-or-profiteering-covid-19-drugs-tests-and-vaccines-pandemic (urging suspension of patent rights in COVID-19 countermeasures to ensure affordability and access); Jennifer Hillman, *Drugs and Vaccines Are Coming—But to Whom?*, FOREIGN AFF. (May 19, 2020), https://www.foreignaffairs.com/articles/world/2020-05-19/drugs-and-vaccines-are-coming-whom (expressing concern that "intellectual property rights could prevent vaccines or drugs from reaching the poor and vulnerable"); *but see* Daniel Hemel & Lisa Larrimore Ouellette, *Pharmaceutical Profits and Public Health Are Not Incompatible*, N.Y. TIMES (Apr. 8, 2020) (arguing that encouraging COVID-19 countermeasure development need not come at the cost of reducing patient access).

[134] *See* 35 U.S.C. § 271(a).

[135] *See* Ariel Cohen, *Senators Worry About COVID-19 Vaccine Affordability, Distribution*, INSIDE HEALTH POLICY (May 14, 2020), https://insidehealthpolicy.com/daily-news/senators-worry-about-covid-19-vaccine-affordability-distribution; Letter from Reps. James E. Clyburn & Carolyn Maloney to Sec. Alex M. Azar II (June 2, 2020), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-06-02.Clyburn%20CBM%20to%20HHS%20re%20Vaccine%20and%20Treatment%20Contracts.pdf; Letter from Rep. Jan Schakowsky et al. to President Donald J. Trump (Feb. 20, 2020), https://freepdfhosting.com/20bf1d75af.pdf.

[136] Pub. L. No. 116-136, § 3203 (2020). Most specifically, this requirement applies to COVID-19 vaccines recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention and to group health plans and health insurance issuers offering group or individual health insurance as defined by PHSA Section 2791. *See id.* § 3203(b)(1), (3). For an analysis of the current federal insurance coverage

ensure that consumers with private health insurance will not pay co-payments for accessing a COVID-19 vaccine, it does not directly address other pricing issues, such as the potential cost to health care providers, health insurance companies, persons without health insurance, or the federal government.[137]

The Coronavirus Preparedness and Response Supplemental Appropriations Act (CPRSA) contains two general provisions related to the affordability of COVID-19 countermeasures. First, products purchased by the federal government using funds appropriated by CPRSA, including vaccines, therapeutics, and diagnostics for COVID-19, "shall be purchased in accordance with Federal Acquisition Regulation guidance on fair and reasonable pricing."[138] Second, CPRSA states that the Secretary of HHS "may take such measures authorized under current law to ensure that vaccines, therapeutics, and diagnostics developed from funds provided in [CPRSA] will be affordable in the commercial market."[139] These general statements were repeated in the appropriations for COVID-19 vaccines and other medical countermeasures in the CARES Act.[140]

This section reviews IP rights provisions under current law that the federal government could use to try to ensure that COVID-19 countermeasures such as a vaccine are accessible and affordable. Other actions that the federal government might hypothetically take—such as additional spending, direct production by federal agencies, contractual guarantees from vaccine manufacturers, governmental negotiation, or price controls—are not discussed, in that such measures do not implicate IP rights and may require additional legislative action beyond the "current law" referenced in CPRSA and the CARES Act.

Patent Rights in Inventions Made with Federal Assistance

Patent Basics

Under the Patent Act,[141] any person who "invents or discovers any new and useful process, machine, manufacture, or composition of matter" may apply for a patent on the invention with the U.S. Patent and Trademark Office (PTO).[142] PTO patent examiners evaluate the application to

requirements for COVID-19 testing, treatments, and vaccinations, *see* CRS Report R46359, *COVID-19 and Private Health Insurance Coverage: Frequently Asked Questions*, by Vanessa C. Forsberg.

[137] It is likely that the federal government will be a primary purchaser and distributor of a COVID-19 vaccine. The federal government currently purchases over half of the pediatric vaccines administered in the United States (primarily for children who are uninsured or eligible for Medicaid). *See* Christoph Diasio, *Pediatric Vaccination: Who Bears The Burden?*, HEALTH AFF. (Feb. 6, 2016), https://www.healthaffairs.org/do/10.1377/hblog20160209.053058/full/; *see generally Vaccines for Children Program (VFC)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 18, 2016), https://www.cdc.gov/vaccines/programs/vfc/index.html; COMMITTEE ON THE EVALUATION OF VACCINE PURCHASE FINANCING IN THE UNITED STATES, FINANCING VACCINES IN THE 21ST CENTURY: ASSURING ACCESS AND AVAILABILITY 4 (2003), https://www.ncbi.nlm.nih.gov/books/NBK221813/pdf/Bookshelf_NBK221813.pdf.

During the 2009 to 2010 H1N1 influenza pandemic, the H1N1 vaccine and ancillary supplies (needles, syringes, etc.) were purchased by the federal government and distributed to health care providers, who could charge only for the administration of the vaccine. *See Questions and Answers on 2009 H1N1 Vaccine Financing*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 30, 2009), https://www.cdc.gov/H1N1flu/vaccination/statelocal/vaccine_financing.htm.

[138] Pub. L. No. 116-123, tit. III, 134 Stat. 146, 149 (2020).

[139] *Id*.

[140] *See* Pub. L. No. 116-136, tit. VIII (2020).

[141] *See* Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792 (1952) (codified as amended at 35 U.S.C. §§ 1-390).

[142] 35 U.S.C. §§ 101, 111.

ensure it meets all the applicable legal requirements to merit the grant of a patent.[143] If the patent examiner concludes that the claimed invention is new, nonobvious, useful, directed at patentable subject matter, and adequately disclosed and claimed,[144] PTO will issue the patent.[145] If granted, patents typically expire 20 years after the initial patent application is filed.[146]

Patents are available for almost every field of technology, including biotechnology, chemistry, computer hardware, electrical engineering, mechanical engineering, and manufacturing processes.[147] In the pharmaceutical context, if an inventor is the first to synthesize a particular chemical that is useful in treating disease, she may seek a patent claiming the chemical itself.[148] That said, patents on a pharmaceutical's active ingredient are only a subset of patents relating to pharmaceuticals and other medical treatments.[149] Particular drug formulations, methods of using the pharmaceutical to treat a particular disease, methods and technologies to administer a pharmaceutical, methods and technologies to manufacture a pharmaceutical, as well as methods and technologies for testing for and diagnosing disease, are all patentable if they meet the Patent Act's requirements.[150]

To encourage innovation, a valid patent holder has the exclusive right to make, use, sell, and import (collectively, "practice") the patented invention in the United States.[151] Patents are thus said to confer a "temporary monopoly" on the patent holder: anyone else who wishes to practice the invention needs to obtain permission from the patent holder to do so (and, typically, pays for that permission).[152] In some situations, patent rights can confer substantial market power on patent holders, enabling them to charge higher-than-competitive prices for the patented product, as a monopolist would.[153] Some empirical studies have found patent rights are among the most important factors driving high prices for pharmaceutical products.[154] At least to some extent,

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[143] *Id.* § 131.

[144] *Id.* §§ 101, 102-103, 112. For a summary of the requirements for patentability, see generally CRS Report R44962, *Patent Law: A Primer and Overview of Emerging Issues*, by Kevin J. Hickey, at 2-4.

[145] 35 U.S.C. § 151, 153.

[146] *Id.* § 154(a)(2).

[147] *See id.* § 101; *Patent Technology Centers Management*, U.S. PATENT & TRADEMARK OFFICE, https://www.uspto.gov/patent/contact-patents/patent-technology-centers-management (last visited May 29, 2020) (listing technological divisions for PTO examiners). For a full discussion of the scope of patentable subject matter, *see generally* CRS Report R45918, *Patent-Eligible Subject Matter Reform in the 116th Congress*, by Kevin J. Hickey.

[148] *See* 35 U.S.C. § 101 (allowing patents on "any new and useful . . . composition of matter").

[149] *See* Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE 1, 4-6 (2012).

[150] *See* Hickey et al., *supra* note 74, at 12-13.

[151] 35 U.S.C. § 271(a). These actions are the core of *direct* patent infringement. There are also a variety of ways to *indirectly* infringe a patent, such as actively inducing another person to infringe a patent or selling a component especially made or especially adapted for an infringing use. *See id.* § 271(b)-(c), (f)-(g).

[152] *See, e.g.*, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 730 (2002) (characterizing patents as a "temporary monopoly"). It should be noted that this usage of "monopoly" is somewhat imprecise, because the exclusive rights provided by IP law do not necessarily confer monopolistic market power in the economic sense—for example, there may be noninfringing substitutes for a patented good in the relevant market. *See* WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 22 (2003) ("[IP] protection creates a monopoly, in the literal sense in which a person has a monopoly in the house he owns but [only] occasionally in a meaningful economic sense as well because there may be no good substitutes for a particular intellectual work.").

[153] *See* FTC v. Actavis, Inc., 570 U.S. 136, 147 (2013) ("[Patent rights] may permit the patent owner to charge a higher-than-competitive price for the patented product.").

[154] *See, e.g.*, Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA: J. AM. MED. ASS'N 858, 861 (2016) ("The most important factor that allows

higher prices are part of the patent system's design, in that they enable inventors to recoup the costs of research and development necessary to produce the invention in the first place.[155] IP law thus seeks to balance the importance of providing incentives to innovate against the costs that IP rights impose on the public in the form of higher prices and reduced competition.[156]

Inventions Made with Federal Assistance

Patent rights initially vest in the individual inventor or inventors, as a general rule.[157] Commonly, however, employees agree by contract to assign their patent rights to inventions made in the course of their employment to their employer, who may seek a patent on an employee's behalf.[158]

When private parties rely on federal assistance to develop an invention, any resulting patent rights will typically be owned by either the U.S. government or the federal contractor, depending on the nature of federal involvement. For inventions made by federal employees during their official duties, the federal government will typically obtain title to the patent.[159] The federal government's general policy for federally owned inventions, under the Stevenson-Wydler Technology Innovation Act[160] and the Federal Technology Transfer Act of 1986,[161] is to encourage their commercialization by licensing the federally owned patent rights to private parties—a process called "technology transfer."[162] Under technology transfer agreements, federal agencies grant private parties the exclusive or nonexclusive right to practice the invention,[163] while the U.S. government retains (1) a "nontransferable, irrevocable, paid-up license . . . to practice the invention . . . by or on behalf of" the United States (the "government-use license");[164] and (2) the

manufacturers to set high drug prices for brand-name drugs is market exclusivity, which arises from 2 forms of legal protection against competition [i.e., patent rights and FDA regulatory exclusivities.]"); *Generic Competition and Drug Prices*, FOOD & DRUG ADMIN. (Nov. 28, 2017), https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm (finding association between generic competition and lower drug prices).

[155] *See, e.g.*, Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974) ("The patent laws promote [the progress of the useful arts] by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development."); Emily Michiko Morris, The *Myth of Generic Pharmaceutical Competition under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 252 (2012) ("[P]harmaceuticals are also widely recognized as one of the industries most dependent on patent protection to recoup its enormous research, development, regulatory, and post-marketing costs . . . .").

[156] *See* Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 429 (1984) ("[D]efining the scope of [patents and copyrights] involves a difficult balance between the interests of authors and inventors in the control and exploitation of their writings and discoveries on the one hand, and society's competing interest in the free flow of ideas, information, and commerce on the other hand . . . ."); Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1031 (2005) ("[Traditionally,] the proper goal of intellectual property law is to give as little protection as possible consistent with encouraging innovation.").

[157] Bd. of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 563 U.S. 776, 785 (2011) ("Our precedents confirm the general rule that rights in an invention belong to the inventor."); *see* 35 U.S.C. §§ 100(f), 101.

[158] *See Roche*, 563 U.S. at 793 (noting "common practice" of assignment of patent rights in inventions from employees to their employer); 35 U.S.C. §§ 118, 152, 261.

[159] *See* 37 C.F.R. § 501.6(a).

[160] Pub. L. No. 96-480, 94 Stat. 2311 (1980).

[161] Pub. L. No. 99-502, 100 Stat. 1785 (1986).

[162] *See* 15 U.S.C. § 3710(a) ("The Federal Government shall strive where appropriate to transfer federally owned or originated technology to State and local governments and to the private sector."); 35 U.S.C. § 209 (conditions for licensing of federally owned inventions).

[163] 35 U.S.C. § 209(a).

[164] *Id.* § 209(d)(1).

power "to terminate the license in whole or in part" based on grounds similar to the conditions for "march-in rights" (discussed below).[165]

The Bayh-Dole Act of 1980 (Bayh-Dole),[166] as amended, applies to inventions that a federal contractor conceives or first reduces to practice during the performance of a funding agreement with a federal agency.[167] Under Bayh-Dole, the federal contractor may elect to retain the patent rights for a federally funded invention.[168] In exchange, however, the contractor provides the federal agency with a government-use license,[169] and the United States retains the authority to grant compulsory licenses to third parties in certain circumstances ("march-in rights").[170] Although Bayh-Dole, by its terms, only applies to federal contractors that are nonprofit organizations or small businesses, long-standing executive practice (codified by regulation) has applied Bayh-Dole to all federal contractors, regardless of size.[171]

Finally, federal laboratories and private parties may enter into cooperative research and development agreements (CRADAs) in which both parties agree to provide services, facilities, equipment, IP, or other resources, but the federal government does not provide federal funding to the nonfederal party.[172] In this situation, ownership of IP rights may depend on the terms of the agreement. That said, the federal laboratory generally has the authority to license existing federally owned IP to a private party as part of a CRADA, as well as to license or assign inventions made in whole or part by a federal employee working under a CRADA.[173] In return, the federal government retains a government-use license[174] and compulsory-licensing authority similar to Bayh-Dole march-in rights.[175]

These general rules for patent ownership are subject to various exceptions and waivers, depending on the agency and circumstances. For example, some agencies (including BARDA and National Institutes of Health [NIH]) have the authority to enter into transactions that are *not* contracts, grants, or cooperative agreements, known as "other transaction" authority.[176] Other

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[165] *Compare id.* § 209(d)(3)(A)-(D) *with* 35 U.S.C. § 203(a)(1)-(4); *see infra* "March-In Rights Under the Bayh-Dole Act (35 U.S.C. § 203)."

[166] Act of Dec. 12, 1980 to Amend the Patent and Trademark Laws (Bayh-Dole Act), Pub. L. No, 96-517, § 6, 94 Stat. 3015, 3018-27 (1980) (codified as amended at 35 U.S.C. ch. 18).

[167] *See* 35 U.S.C. §§ 201(b), (e).

[168] *Id.* § 202(a).

[169] *Id.* § 202(c)(4).

[170] *Id.* § 203; *see generally* Hickey et al., *supra* note 74, at 17.

[171] 37 C.F.R. § 401.1(b) (Bayh-Dole regulations apply "to all funding agreements with business firms regardless of size"); Exec. Order No. 12591, Facilitating Access to Science & Technology, 52 Fed. Reg. 13,414, 13,414 (Apr. 10, 1987) (granting "to all contractors, regardless of size, the title to patents made in whole or in part with Federal funds, in exchange for royalty-free use by or on behalf of the government").

[172] 15 U.S.C. § 3710a(a)(1) (CRADA authority); *id.* § 3710a(d)(1) (CRADA definition).

[173] *See id.* § 3710a(a)(2), (b)(1)-(2); 35 U.S.C. §§ 207, 209.

[174] 15 U.S.C. § 3710a(b)(1)(A), (2).

[175] *See id.* § 3710a(b)(1)(C)(i)-(iii) (grounds for compulsory licensing of inventions "made in whole or in part by a [federal] laboratory employee" under a CRADA). In the case of inventions "made solely by [the private collaborating party's] employee" in the course of a CRADA, the federal agency retains a government-use license, but need not impose march-in rights. *Compare id.* § 3710a(b)(1) *with* 3710a(b)(2).

[176] 42 U.S.C. § 247d-7e(c)(5) (granting Secretary of HHS authority to enter into other transactions for BARDA projects); *id.* § 282(n) (granting director of NIH other transaction authority in certain contexts). Because NIAID is one of NIH's research institutes, *see id.* § 281(b)(6), this authority could apply to NIAID projects approved by the Director of NIH. In the case of COVID-19 projects, NIH authority for use of other transactions when "urgently required to respond to a public health threat" appears applicable. *See id.* § 282(n)(1)(C). For a general overview of other

transactions are exempt from many statutory provisions and procurement regulations, including Bayh-Dole's requirements.[177]

Thus, for other transactions, the allocation of IP rights between the government and private contracting entities will depend on the agreement. For example, BARDA's template for other transactions includes contractual patent provisions much like those of Bayh-Dole, including march-in rights provisions.[178] These patent provisions are "fluid and negotiable," however, and may be different for particular transactions.[179] In addition, both Stevenson-Wydler's and Bayh-Dole's requirements contain specific exceptions. For example, Bayh-Dole's patent provisions do not apply to contractors located outside the United States, nor in "exceptional circumstances," including if necessary "to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions."[180]

Governmental Compulsory Patent Licenses

As explained above, a patent holder generally has the exclusive right to make, use, sell, and import an invention.[181] Thus, any other person who wishes to practice that invention will ordinarily need a license (i.e., permission) from the patent holder, or else be exposed to legal liability. In certain cases, however, patents may be subject to a "compulsory license," which allows another person to practice the invention without the consent of the patent holder.[182] Compulsory licenses require the sanction of a governmental entity and the payment of compensation to the patent holder.[183] Compulsory licenses differ from ordinary licenses in two important respects. First, the person seeking to use the invention need not obtain permission from the patent holder.[184] Second, the compensation paid to the patent holder is determined by operation of law, not by private contractual negotiations between the licensee and the patent holder.[185]

March-In Rights Under the Bayh-Dole Act (35 U.S.C. § 203)

Although Bayh-Dole generally allows federal contractors to take title to patents on inventions created with federal funding,[186] the federal government retains the authority to "march in" and

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transactions, see U.S. GOVERNMENT ACCOUNTABILITY OFFICE, USE OF 'OTHER TRANSACTION' AGREEMENTS LIMITED AND MOSTLY FOR RESEARCH AND DEVELOPMENT ACTIVITIES 3-12 (2016), https://www.gao.gov/assets/680/674534.pdf [hereinafter GAO OTA REPORT].

[177] *See* GAO OTA REPORT, *supra* note 176, at 4-5; 35 U.S.C. § 201(b) (defining "funding agreements" subject to Bayh-Dole to include "any contract, grant, or cooperative agreement").

[178] *See* Other Transaction for Advanced Research (OTAR) Template, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY, https://www.phe.gov/about/amcg/otar/Documents/otar-consortium.pdf (last visited May 31, 2020), at pp. 16-21 [hereinafter BARDA OTA Template]; *see generally* Other Transaction Agreements, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY, https://www.phe.gov/about/amcg/otar/Pages/default.aspx (last visited May 31, 2020).

[179] BARDA OTAR Template, *supra* note 178, at 16.

[180] *See* 35 U.S.C. §§ 200, 202(a)(ii),

[181] *Id*. § 271(a).

[182] *See generally* Hickey et al., *supra* note 74, at 16-17.

[183] *Id*. at 1.

[184] *See* Hickey et al., *supra* note 74, at 16.

[185] *Id*.

[186] 35 U.S.C. § 202(a)-(b).

grant compulsory licenses to third parties in some circumstances.[187] Specifically, the federal agency that provided the funding may require the federal contractor to grant a patent license to a third party if the agency determines that either

> (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
>
> (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
>
> (3) action is necessary to meet requirements for public use specified by federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
>
> (4) action is necessary because the agreement [to prefer U.S. manufacturing of the invention by the contractor's exclusive licensees] has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement [to prefer U.S. manufacturing].[188]

A license granted under Bayh-Dole's march-in provisions must be "upon terms that are reasonable under the circumstances,"[189] which may require that the licensee pay compensation to the patent holder (i.e., the federal contractor or its assignee).[190]

The federal government has never exercised march-in rights under Bayh-Dole.[191] Advocacy groups have petitioned NIH several times to exercise march-in rights based on the high prices of certain drugs developed with federal funding, such as treatments for HIV/AIDS.[192] NIH has rejected these petitions, contending that pricing concerns alone are insufficient to exercise march-in rights—so long as the invention is on the market and available to patients.[193] In the context of a pandemic like COVID-19, the "health or safety needs" language would appear to provide a possible basis for the exercise of march-in rights, should the funding agency determine that compulsory licensing is necessary to address public health needs unmet by a federal contractor.[194]

Governmental Use Rights (28 U.S.C. § 1498)

A broader statutory authority than march-in rights, 28 U.S.C. § 1498 (Section 1498), applies to any patented invention—not just inventions made with federal funding.[195] Under Section 1498,

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[187] *Id*. § 203.

[188] *Id*. § 203(a)(1)-(4).

[189] *Id*. § 202(a).

[190] *See id* § 203(a); Jennifer Penman & Fran Quigley, *Better Late than Never: How the U.S. Government Can and Should Use Bayh-Dole March-in Rights to Respond to the Medicines Access Crisis*, 54 WILLAMETTE L. REV. 171, 178 (2017).

[191] *Id*.

[192] *See id*. at 8-10 (reviewing petitions to exercise march-in rights).

[193] *See, e.g.*, National Institutes of Health, Office of the Director, *In the Case of Norvir Manufactured by Abbott Laboratories, Inc.* (July 29, 2004), https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf, at pp. 5-6.

[194] 35 U.S.C. § 203(a)(2). A federal contractor adversely affected by the exercise of march-in rights may challenge an agency's determination through an administrative process, *see* 37 C.F.R. § 401.6, and may appeal an adverse determination through a petition in the U.S. Court of Federal Claims, *see* 35 U.S.C. § 203(b).

[195] 28 U.S.C. § 1498(a) (reaching "any invention described in and covered by a patent of the United States"). Section 1498 does not apply to patent rights granted by other nations.

sometimes described as an "eminent domain" provision for patents,[196] the U.S. government has the authority to use or manufacture any patented invention "without license."[197] In practice, this means that if the U.S. government determines that it needs to practice an invention, it need not ask permission from the patent holder to do so, and—despite the existence of the patent—courts will not order the government to cease infringing activity.[198] The patent holder, however, has the right to sue in the U.S. Court of Federal Claims for "reasonable and entire compensation" for the government's use of the patented invention.[199] In effect, then, Section 1498 allows the United States to issue itself a compulsory license to make and use any patented invention without obtaining the permission of the patent holder, in exchange for consenting to liability in a suit seeking reasonable compensation for the government's use.[200]

In the context of COVID-19 medical countermeasures, the U.S. government could rely on Section 1498 to make and use any patented invention without the consent of the patent holder. Because Section 1498 extends to infringement "by a contractor, a subcontractor, or any person, firm, or corporation for the [U.S.] Government and with the authorization or consent of the [U.S.] Government,"[201] the federal government could also extend its Section 1498 authority to the actions of private entities by authorizing them to practice a patented invention on behalf of the government.

Targeted Legislation and the Takings Clause

U.S. patent rights were created by an act of Congress. Thus, should patent rights inhibit access to or affordability of COVID-19 countermeasures such as a vaccine, and should Congress conclude that existing legal authorities are insufficient, targeted legislation is a possible option. Although the U.S. Constitution grants Congress the authority to create a patent system,[202] it does not require Congress to do so. Congress therefore has wide discretion in designing the patent system's scope and operation.[203] So long as it operates prospectively (and consistent with its international treaty obligations),[204] Congress may exclude certain technologies from patent protection. For example, a provision in the 2011 Leahy-Smith America Invents Act prohibits the PTO from issuing a patent on inventions "directed to or encompassing a human organism."[205]

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[196] *See, e.g.*, Motorola, Inc. v. United States, 729 F.2d 765, 768 (Fed. Cir. 1984) ("The theoretical basis for [Section 1498] recovery is the doctrine of eminent domain.").

[197] 28 U.S.C. § 1498(a).

[198] Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis, 583 F.3d 1371, 1375 (Fed. Cir. 2009); *Motorola*, 729 F.2d at 768 n.3.

[199] 28 U.S.C. § 1498(a); *see generally* Leesona Corp. v. United States, 599 F.2d 958, 966-69 (Ct. Cl. 1979).

[200] *See* Amanda Mitchell, *Tamiflu, the Takings Clause, and Compulsory Licenses: An Exploration of the Government's Options for Accessing Medical Patents*, 95 CAL. L. REV. 535, 541-42 (2007) (analogizing Section 1498 to a compulsory license).

[201] 28 U.S.C. § 1498(a).

[202] U.S. CONST. art. I, § 8, cl. 8.

[203] *See, e.g.*, McClurg v. Kingsland, 42 U.S. 202, 206 (1843) ("[T]he powers of Congress to legislate upon the subject of patents is plenary by the terms of the Constitution, and as there are no restraints on its exercise, there can be no limitation of their right to modify them at their pleasure, so that they do not take away the rights of property in existing patents."). There are, of course, some limits on the power granted Congress in the IP Clause. *See generally, e.g.*, Eldred v. Ashcroft, 537 U.S. 186, 199-208 (2003); Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 5-10 (1966).

[204] *See infra* note 211 and accompanying text.

[205] Pub. L. No, 112-29, § 33, 125 Stat. 284, 340 (2011).

When legislation operates retroactively to invalidate a patent or diminish patent rights, however, it raises issues under the Takings Clause of the Fifth Amendment to the U.S. Constitution. The Takings Clause states that if "private property [is] taken for public use" by the U.S. government, it must provide "just compensation."[206] The Supreme Court has suggested several times that patents are private property under the Takings Clause,[207] but it has never held so explicitly. Presuming that patents are private property under the Fifth Amendment,[208] legislation that retroactively impairs patent rights could give rise to a constitutional claim for just compensation.[209] Recognizing this, Congress has often provided for compensation in past legislation that has retroactively invalidated patents. For example, the Atomic Energy Act of 1954 "revoked" existing patents on "any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon," while providing a process to provide just compensation to any such patent holder.[210]

If Congress seeks to preclude the exercise of exclusive patent rights over COVID-19 medical countermeasures, it could pass legislation preventing the PTO from issuing such patents, or invalidating already issued patents relating to countermeasures. In the latter case, some mechanism for compensation to the patent holder might be required under the Takings Clause. In either case, such legislation could raise issues under the United States' treaty obligations, including the treaty on Trade-Related Aspects of Intellectual Property Rights of the Marrakesh Agreement establishing the World Trade Organization (WTO), in which WTO members agree to make patents available in "all fields of technology," with some exceptions.[211] In addition, limitations on patent rights could reduce incentives to create and develop medical countermeasures against COVID-19.[212]

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[206] U.S. CONST. amend. V.

[207] *Compare* James v. Campbell, 104 U.S. 356, 357-58 (1881) ("[By issuing a patent, the United States] confers on the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation . . . ."), *with* Oil States Energy Servs. v. Greene's Energy Grp., 138 S. Ct. 1365, 1379 (2018) (holding that the grant of a patent is matter of public rights but stating that "our decision should not be misconstrued as suggesting that patents are not property for purposes of the Due Process Clause or the Takings Clause.").

[208] Legal academics have debated this point. *Compare* Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause*, 87 B.U. L. REV. 689 (2007), *with* Davida H. Isaacs, *Not All Property Is Created Equal: Why Modern Courts Resist Applying the Takings Clause to Patents, and Why They Are Right to Do So*, 15 GEO. MASON L. REV. 1 (2007). Notably, in a recent Federal Circuit case, the PTO conceded that patents were "private property" under the Takings Clause. *See* Celgene Corp. v. Peter, 931 F.3d 1342, 1358 (Fed. Cir. 2019), *petition for cert. filed*, No. 19-1074 (U.S. Feb. 26, 2020).

[209] *See, e.g.*, *Celgene*, 931 F.3d at 1358 (rejecting claim that retroactive application of inter partes review procedures is an unconstitutional taking of patent rights). For analyses of potential Takings Clause claims as applied to patents, see generally, e.g., Gregory Dolin & Irina D. Manta, *Taking Patents*, 73 WASH. & LEE L. REV. 719 (2016); Joshua I. Miller, *28 U.S.C. § 1498(a) and the Unconstitutional Taking of Patents*, 13 YALE J.L. & TECH. 1 (2010); Christopher S. Storm, *Federal Patent Takings*, 2 J. BUS. ENTREPRENEURSHIP & L. 1 (2008); Justin Torres, *The Government Giveth, and the Government Taketh Away: Patents, Takings, and 28 U.S.C. § 1498*, 63 N.Y.U. ANN. SUR. AM. L. 315 (2007); Jesse S. Chui, *To What Extent Can Congress Change the Patent Right Without Effecting a Taking?*, 34 HASTINGS CONST. L.Q. 447 (2007); Shubha Ghosh, *Toward A Theory of Regulatory Takings for Intellectual Property: The Path Left Open After* College Savings v. Florida Prepaid, 37 SAN DIEGO L. REV. 637 (2000).

[210] 42 U.S.C. §§ 2181(a), 2187.

[211] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 (1994), https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm, at art. 27. For analysis of how the limits of TRIPS might apply to exclusions from patent protection or compulsory licensing in the COVID-19 pandemic, see CRS Legal Sidebar LSB10436, *COVID-19: International Trade and Access to Pharmaceutical Products*, by Nina M. Hart.

[212] *See, e.g.*, Fred Reinhart, *Exercising Bayh-Dole March-in Rights Would Handicap Covid-19 Innovation*, STAT (May 4, 2020), https://www.statnews.com/2020/05/04/bayh-dole-march-in-rights-handicap-covid-19-innovation/; James

The PREP Act: Liability and Compensation for COVID-19 Vaccine Injuries

To encourage the expeditious development and deployment of medical countermeasures during a public health emergency, the PREP Act[213] authorizes the Secretary of HHS to limit legal liability for losses relating to the administration of medical countermeasures, including diagnostics, treatments, and vaccines.[214] In a declaration effective February 4, 2020 (the COVID-19 PREP Act Declaration), the Secretary of HHS invoked the PREP Act and declared COVID-19 to be a public health emergency warranting liability protections for covered countermeasures.[215] Under the COVID-19 PREP Act Declaration, covered persons are generally immune from legal liability for losses relating to the administration or use of covered countermeasures against COVID-19.[216] The sole exception to PREP Act immunity is for death or serious physical injury caused by "willful misconduct."[217] However, individuals who die or suffer serious injuries directly caused by the administration of covered countermeasures may be eligible to receive compensation through an HHS administrative process called the Countermeasures Injury Compensation Program (CICP).[218]

Courts have characterized PREP Act immunity as "sweeping."[219] It applies to all types of legal claims under state and federal law.[220] For example, under state tort law, individuals who suffer injuries caused by the intentional or negligent acts or omissions of another person may generally sue that person to recover monetary compensation.[221] Thus, in the health care context, if a health care provider negligently administers a drug or device that causes a foreseeable injury to a patient, the injured person may be able to sue the provider for compensation.[222]

Federal laws such as the PREP Act may preempt state tort laws—as well as other state and federal laws—in certain contexts.[223] Preemptive federal legislation displaces state law to alter the usual liability rules or immunize certain individuals from liability.[224] In the PREP Act, Congress made the judgment that, in the context of a public health emergency, immunizing certain persons and

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Edwards, *We Won't Stop Coronavirus Without IP*, IPWATCHDOG (Mar. 10, 2020), https://www.ipwatchdog.com/2020/03/10/wont-stop-coronavirus-without-ip/id=119735/.

[213] Pub. L. 109-148, div. C, 119 Stat. 2680, 2818-32 (2005) (codified as amended at 42 U.S.C. §§ 247d-6d, 247d-6e).

[214] 42 U.S.C. § 247d-6d(b)(1).

[215] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (Mar. 17, 2020) (effective Feb. 4, 2020) [hereinafter COVID-19 PREP Act Declaration].

[216] *Id.* at 15,201-02; 42 U.S.C. § 247d-6d(a)(1).

[217] 42 U.S.C. § 247d-6d(d)(1).

[218] *Id.* § 247d-6e; 42 C.F.R. pt. 110.

[219] *See* Parker v. St. Lawrence Cty. Pub. Health Dep't, 102 A.D.3d 140, 143 (N.Y. App. Div. 2012).

[220] 42 U.S.C. § 247d-6d(a)(1).

[221] *See generally* CRS In Focus IF11291, *Introduction to Tort Law*, by Kevin M. Lewis.

[222] *Id.* at 1.

[223] *See generally* CRS Report R45825, *Federal Preemption: A Legal Primer*, by Jay B. Sykes and Nicole Vanatko.

[224] *See, e.g.*, CRS Legal Sidebar LSB10461, *Federal Legislation Shielding Businesses and Individuals from Tort Liability: A Legal and Historical Overview*, by Kevin M. Lewis (summarizing federal statutes that either insulate particular entities from tort liability or otherwise displace state tort law).

entities from liability was necessary to ensure that potentially life-saving countermeasures will be efficiently developed, deployed, and administered.[225]

So long as the COVID-19 PREP Act Declaration remains in effect, COVID-19 vaccine manufacturers, distributors, and qualified health care providers are generally immune from legal liability for losses relating to the use or administration of that vaccine. Instead, individuals who are injured or die as a result of receiving a COVID-19 vaccine may seek compensation through CICP. This section explains the scope of this PREP Act immunity as it applies to COVID-19 countermeasures, including vaccines, as well as the contours and availability of CICP compensation.

The Public Readiness and Emergency Preparedness Act

Scope of Immunity from Liability

For the PREP Act to apply, the Secretary of HHS must determine that a disease or other threat to health constitutes a public health emergency, or that there is a credible risk of such an emergency.[226] The Secretary shall consider the desirability of encouraging the design, development, testing, manufacture, and use of countermeasures in determining whether to issue a PREP Act declaration.[227] The Secretary must publish the PREP Act declaration in the *Federal Register* and identify, for each countermeasure, the particular disease, time period, population, and geographical area that the declaration covers.[228]

If within the scope of the declaration, the PREP Act immunizes a covered person from legal liability for all claims for loss relating to the administration or use of a covered countermeasure.[229] The requirements for PREP Act immunity thus break down into four elements: (1) the individual or entity must be a "covered person"; (2) the legal claim must be for a "loss"; (3) the loss must have a "causal relationship" with the administration or use of a covered countermeasure; and (4) the medical product that caused the loss must be a "covered countermeasure."

"Covered Persons"

The PREP Act defines covered persons to include (i) the United States; (ii) manufacturers and distributors of covered countermeasures; (iii) "program planners"; and (iv) "qualified persons"

[225] *See, e.g.*, 151 CONG. REC. H12264 (daily ed. Dec. 18, 2005) (statement of Rep. Deal) ("Unfortunately, there is no business model that would have vaccine manufacturers take on the tremendous liability risks to produce [a pandemic flu] vaccine. We must address this concern or we will have none. It's really that simple. . . . What the [PREP Act] does is provide authority to the Secretary[:] the ability to declare limited liability protection. The Secretary can use these declarations to make sure the vaccine gets developed and to make sure doctors are willing to give it when the time comes.").

[226] 42 U.S.C. § 247d-6d(b)(1).

[227] *Id.* § 247d-6d(b)(6). A PREP Act declaration is distinct from the Secretary's power to declare a public health emergency under Section 319 of the PHSA, which has a separate set of legal implications. *Id.* § 247d; *see generally* U.S. Dep't of Health and Human Servs., Office of the Assistant Sec. for Preparedness and Response, Public Health Emergency Declaration (Nov. 26, 2019) (describing powers of Secretary of HHS under Section 319). The Secretary of HHS made the Section 319 declaration for COVID-19 on January 31, 2020. Alex M. Azar II, Sec'y of the Dep't of Health and Human Servs., Determination that a Public Health Emergency Exists, https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx (Jan. 31, 2020).

[228] 42 U.S.C. § 247d-6d(b)(1)-(3).

[229] *Id.* § 247d-6d(a)(1).

who prescribe, administer, or dispense covered countermeasures.[230] Program planners include Indian Tribes, state governments, and local governments who supervise programs that dispense, distribute, or administer covered countermeasures, or provide policy guidance, facilities, and scientific advice on the administration or use of such countermeasures.[231] Qualified persons include licensed health professionals and other individuals authorized to prescribe, administer, or dispense covered countermeasures under state law, as well as other categories of persons identified by the Secretary in a PREP Act declaration.[232] Employees and agents of all these persons and entities are also covered persons.[233]

Covered "Claims for Loss"

PREP Act immunity reaches "all claims for loss" under federal and state law.[234] 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.[235] This language would seem to include, at a minimum, most state law tort, medical malpractice, and wrongful death claims resulting from the administration of covered countermeasures.

Causal Relationship Between the Loss and the Countermeasure

To be preempted by the PREP Act, the claims for loss must have a causal relationship to the administration and use of a covered countermeasure.[236] As with the other elements, the PREP Act's causation language sweeps broadly. PREP Act immunity applies to any claim for loss that has "a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use" of a covered countermeasure.[237]

"Covered Countermeasures"

Finally, the medical product at issue must be a covered countermeasure. The PREP Act specifies three general types of covered countermeasures: (i) a qualified "pandemic or epidemic product"; (ii) a "security countermeasure"; and (iii) a drug, biological product, or device that FDA has authorized for emergency use.[238] As discussed below, Congress recently added a fourth covered countermeasure category specifically for respiratory protective devices.[239]

A *pandemic or epidemic product* includes any drug, biological product, or device developed "to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic."[240] In addition, drugs,

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[230] *Id*. § 247d-6d(i)(2).

[231] *Id*. § 247d-6d(i)(6).

[232] *Id*. § 247d-6d(i)(8).

[233] *Id*. § 247d-6d(i)(2)(B)(v).

[234] *Id*. § 247d-6d(a)(1).

[235] *Id*. § 247d-6d(a)(2)(A)(i)-(iv).

[236] *Id*. § 247d-6d(a)(1).

[237] *Id*. § 247d-6d(a)(2)(B).

[238] *Id*. § 247d-6d(i)(1)(A)-(C).

[239] *Id*. § 247d-6d(i)(1)(D); *see infra* "Recent Congressional Actions on COVID-19 Countermeasures Liability."

[240] 42 U.S.C. § 247d-6d(i)(7)(A)(i). The PREP Act incorporates the general definitions of "drug," "biological product,"

biological products, or devices uses to treat the side effects of a pandemic or epidemic product, or to enhance their effects, may themselves be covered countermeasures.[241] In either case, to be a covered countermeasure, the pandemic or epidemic product must be approved, licensed, or authorized for emergency use by FDA.[242]

A *security countermeasure* refers to a drug, biological product, or device used "to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent" identified by the Secretary of Homeland Security as a material threat to national security.[243]

The *emergency use* category of covered countermeasure includes drugs, biological products, and devices that FDA has authorized for use outside its ordinary regulatory process through an EUA.[244] FDA has made wide use of its emergency authorities in response to the COVID-19 pandemic, issuing EUAs for certain in vitro diagnostic products (i.e., tests for COVID-19), antibody tests, personal protective equipment (e.g., respirators and face shields), devices modified for use as ventilators, and therapeutic drugs.[245]

Thus, so long as FDA licensed or authorized a COVID-19 vaccine, it would be a covered countermeasure within the scope of the PREP Act, either as a "pandemic or epidemic product" or through the emergency use category in the case of authorization through an EUA. Prior to licensure or authorization of a COVID-19 vaccine, the PREP Act would also afford liability protections for injuries that may occur in the clinical testing process, if the vaccine is "the object of research for possible use" as a pandemic or epidemic product and subject to an investigational use exemption.[246]

The Willful Misconduct Exception

If a claim for loss is within the PREP Act's scope, a covered person is generally immune from legal liability.[247] The "sole exception" to immunity is when a covered person proximately causes death or serious physical injury to another person through willful misconduct.[248] A serious physical injury must be life threatening, permanently impair a body function, permanently damage a body structure, or require medical intervention to avoid such permanent impairment or damage.[249] Willful misconduct requires that the covered person acted (i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; *and* (iii) in disregard of a

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and "device" under the FD&C Act and PHSA. *See* 21 U.S.C. § 321(g)(1), (h); 42 U.S.C. § 262(i).

[241] 42 U.S.C. § 247d-6d(i)(7)(A)(ii)-(iii).

[242] *Id*. § 247d-6d(i)(7)(B)(i), (iii).

[243] *Id*. §§ 247d-6b(c)(1)(B), 247d-6d(i)(1)(B).

[244] *Id*. § 247d-6d(i)(1)(C); *see supra* "Emergency Use Authorizations Before Approval."

[245] *Emergency Use Authorization: Coronavirus Disease 2019 (COVID-19) EUA Information*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas (last updated June 1, 2020) (listing FDA's current EUAs for COVID-19 diagnostics, antibody tests, personal protective equipment, therapeutics, and ventilators).

[246] 42 U.S.C. § 247d-6d(i)(7)(B)(ii).

[247] *Id*. § 247d-6d(a)(1).

[248] *Id*. § 247d-6d(d)(1). In the case of actions by or against the United States, the PREP Act shall not "be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law or to waive sovereign immunity or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or employees under any other law . . . ." *Id*. § 247d-6d(f).

[249] *Id*. § 247d-6d(i)(10).

known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.[250]

The process by which an injured person (or their representative) may prove willful misconduct under the PREP Act is limited in several ways. Before filing a suit claiming willful misconduct, the injured person must first seek compensation through CICP, and they cannot sue if they elect to receive that compensation.[251] If they choose to file a lawsuit, injured persons may sue only in the U.S. District Court for the District of Columbia.[252] Such lawsuits are assigned to a three-judge panel, must meet heightened standards for pleading and discovery, and are subject to procedural provisions generally favorable to defendants.[253] Injured persons must prove willful misconduct by clear and convincing evidence,[254] a higher standard of proof than a typical civil case. Recovery for noneconomic damages such as pain and suffering is limited.[255]

In addition to these procedural and substantive limitations, the PREP Act contains two statutory defenses to claims of willful misconduct. First, program planners and qualified persons cannot be found to have engaged in willful misconduct if they "acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure," and notify either the Secretary or a state or local health authority of the injury or death allegedly caused by the countermeasure within seven days.[256] Second, countermeasure manufacturers and distributors may rely on regulatory compliance as a complete defense to a "willful misconduct" allegation.[257] When the act or omission alleged to be willful misconduct is "subject to regulation" under the PHSA or the FD&C Act, an injured person cannot succeed on a willful misconduct claim unless the Secretary of HHS or the Attorney General has brought certain "enforcement actions" against the manufacturer or distributor that result in the imposition of particular penalties.[258]

The Countermeasures Injury Compensation Program

An individual seriously injured or killed by the administration of a covered countermeasure, whether or not as a result of willful misconduct, may seek compensation through CICP.[259] CICP is a regulatory process administered by HHS's Health Resources and Services Administration.[260]

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[250] *Id*. § 247d-6d(c)(1)(A).

[251] *Id*. § 247d-6e(d)(1), (5).

[252] *Id*. § 247d-6d(e)(1).

[253] *See id*. § 247d-6d(e)(3)-(6), (10).

[254] *Id*. § 247d-6d(c)(3).

[255] *Id*. § 247d-6d(e)(7)-(8).

[256] *Id*. § 247d-6d(c)(4).

[257] *Id*. § 247d-6d(c)(5).

[258] *Id*. § 247d-6d(c)(5)(A)(i)-(ii). The necessary "enforcement actions" include criminal prosecutions, civil monetary proceedings based on willful misconduct, mandatory product recalls, or revocations, suspensions or withdrawals, based on willful misconduct, of FDA approval, licensure, or authorization. *Id*. § 247d-6d(c)(5)(B)(i). Before a willful misconduct claim can proceed, the enforcement action must conclude with the imposition of a "covered remedy" such as a criminal conviction, an injunction, a civil monetary payment, a product recall, or a suspension or withdrawal of FDA approval or licensure. *Id*. § 247d-6d(c)(5)(B)(ii).

[259] *Id*. § 247d-6e(a)-(b).

[260] *See generally Countermeasure Injury Compensation Program*, HEALTH RESOURCES & SERVS. ADMIN., https://www.hrsa.gov/cicp/index.html (last visited May 28, 2020).

HHS regulations govern CICP's procedures and eligibility determinations.[261] In general, eligible individuals (or their survivors) who suffer death or serious physical injury directly caused by the administration of a covered countermeasure may receive reimbursement through CICP for reasonable medical expenses, loss of employment income, and survivor benefits in the case of death.[262] Serious physical injuries under CICP are generally limited to those that warrant hospitalization or lead to a significant loss of function or disability.[263] Congress funds CICP compensation through emergency appropriations to the Covered Countermeasure Process Fund.[264]

CICP is distinct from the National Vaccine Injury Compensation Program,[265] which provides compensation for injuries caused by most vaccines routinely administered in the United States, such as childhood vaccines (e.g., MMR, polio, hepatitis A) and nonpandemic seasonal influenza vaccines.[266] By contrast, CICP only applies to countermeasures covered by a PREP Act declaration of a public health emergency, such as those issued for COVID-19, pandemic influenza (e.g., the 2009 H1N1 "swine flu"), and the Ebola virus.[267]

The COVID-19 PREP Act Declaration

On March 10, 2020, the Secretary of HHS invoked the PREP Act and determined that COVID-19 constitutes a public health emergency.[268] The COVID-19 PREP Act Declaration therefore authorizes PREP Act immunity for the "manufacture, testing, development, distribution, administration, and use" of covered countermeasures.[269] This immunity applies to all covered persons as defined in the PREP Act, including any person authorized by state and local public health agencies (or an EUA) to "prescribe, administer, deliver, distribute or dispense" covered countermeasures.[270] Covered countermeasures include "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19."[271] The "administration" of a covered countermeasure includes "physical provision of the countermeasures" to patients, as well as "activities and decisions directly relating to . . . delivery, distribution and dispensing of" the countermeasures.[272] The declaration provides PREP Act immunity "without geographic limitation," beginning on February 4, 2020, and ending as late as October 1, 2025.[273]

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[261] *See* 42 C.F.R. pt. 110.

[262] 42 U.S.C. § 247d-6e(a), (b), (e)(3), (e)(5); 42 C.F.R. § 110.2(a).

[263] 42 C.F.R. § 110.3(z).

[264] 42 U.S.C. § 247d-6e(a).

[265] *See* 42 U.S.C. §§ 300aa-10 to 300aa-34; 42 C.F.R. pt. 100.

[266] *See National Vaccine Injury Compensation Program: Covered Vaccines*, HEALTH RESOURCES & SERVS. ADMIN, https://www.hrsa.gov/vaccine-compensation/covered-vaccines/index.html (last updated Mar. 2020).

[267] *See* HEALTH RESOURCES & SERVS. ADMIN, COUNTERMEASURES INJURY COMPENSATION PROGRAM: FACT SHEET (Oct. 2017), https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicpfactsheet.pdf.

[268] COVID-19 PREP Act Declaration, 85 Fed. Reg. at 15,201.

[269] *Id*.

[270] *Id*. at 15,201-02.

[271] *Id*. at 15,202.

[272] *Id*.

[273] *See id*.

Recent Congressional Actions on COVID-19 Countermeasures Liability

Three recent congressional enactments in response to the COVID-19 pandemic, all now signed into law, relate to the scope of immunity for individuals engaged in the COVID-19 response.

Section 6005 of the Families First Coronavirus Response Act[274] and Section 3103 of the CARES Act[275] amend the PREP Act to clarify that certain "personal respiratory protective devices" (such as N95 respirators) are covered countermeasures. To be covered by the PREP Act, the respiratory protective device must be (i) approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 C.F.R. Part 84; and (ii) determined by the Secretary of HHS to be a priority for use during a public health emergency.[276]

Section 3215 of the CARES Act contains an independent immunization from liability for volunteer health care professionals responding to the COVID-19 pandemic. Under Section 3215, licensed health care professionals are generally immune from state or federal liability for harm they cause while providing health care services in response to the COVID-19 public health emergency as a volunteer, if they act within the scope of their license and in good faith.[277] There are two exceptions to this immunity: (1) if the volunteer health care professional's acts constituted willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the individual harmed;[278] or (2) if the volunteer health care professional rendered health care services under the influence of drugs or alcohol.[279] Section 3215 immunity may overlap with PREP Act immunity, or extend beyond it in some cases (e.g., situations not involving a covered countermeasure).

Finally, both the CARES Act and CPRSA appropriate funding that HHS may use for the Covered Countermeasure Process Fund, upon which CICP relies. CPRSA appropriates $3.1 billion to the Secretary of HHS to respond to COVID-19, including the development and purchase of countermeasures and vaccines, while allowing these funds to "be transferred to, and merged with" the Covered Countermeasure Process Fund.[280] The CARES Act appropriates $27 billion to the Secretary of HHS for similar purposes, again providing that the Secretary may transfer these funds to the Covered Countermeasure Process Fund.[281]

[274] Pub. L. No. 116-127, § 6005, 134 Stat. 178, 207 (2020).

[275] Pub. L. No. 116-136, § 3103 (2020).

[276] 42 U.S.C. § 247-6d(i)(1)(D). Prior to these amendments, FDA issued an EUA on March 2, 2020 for the use of NIOSH-approved filtering respirators intended for general use in healthcare settings, and expressed its view that the PREP Act covered these respirators prior to the amendment because of their medical use. *See* Letter from Denise M. Hinton, Chief Scientist, FDA, to Robert R. Redfield, Director Centers for Disease Control and Prevention (March 28, 2020), https://www.fda.gov/media/135763/download.

[277] Pub. L. No. 116-136, § 3215(a).

[278] *Id*. § 3215(b)(1).

[279] *Id*. § 3215(b)(2).

[280] Pub. L. No. 116-123, tit. III, 134 Stat. 146, 149 (2020).

[281] Pub. L. No. 116-136, tit. VIII.

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