

# TAKING A SHOT AT VACCINE HESITANCY: USING CRIMINAL LIABILITY WITHIN RESEARCH REGULATIONS TO INCREASE TRUST IN VACCINES

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## INTRODUCTION

Despite the overwhelming evidence that the Covid-19 vaccines are safe and effective,<sup>1</sup> as of March 16, 2022, more than eighteen percent of the vaccine-eligible American population remains unvaccinated.<sup>2</sup> Vaccine skepticism, however, did not originate with the Covid-19 vaccine.<sup>3</sup> The reasons provided by individuals hesitant or

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1. See e.g., Gabor David Kelen, Lisa Maragakis, *Is the COVID-19 Vaccine Safe?*, *JOHNS HOPKINS MED.* (Jan. 4, 2022), <https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/is-the-covid19-vaccine-safe> (“Yes. The two mRNA vaccines, Pfizer and Moderna, authorized by the U.S. Food and Drug Administration (FDA) and recommended by the Centers for Disease Control and Prevention (CDC), are very safe and very good at preventing serious or fatal cases of COVID-19.”); *Coronavirus (COVID-19) vaccines*, NAT’L HEALTH SERV. (Feb. 10, 2022), <https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/coronavirus-vaccine/> (showing British health authorities discussing the safety and effectiveness of the Covid-19 vaccines).

2. *Covid Data Tracker*, CTRS. FOR DISEASE CONTROL AND PREVENTION, [https://covid.cdc.gov/covid-data-tracker/#vaccinations\\_vacc-total-admin-rate-total](https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total) (last visited Mar. 17, 2022).

3. See e.g., Stacie L. Benoit & Rachel F. Mauldin, *The “anti-vax” movement: a quantitative report on vaccine beliefs and knowledge across social media*, 21 *BMC PUBLIC HEALTH* 2106, at 2 (Nov. 2021), <https://doi.org/10.1186/s12889-021-12114-8> (discussing the long history of vaccine skepticism including writings from 1722, resistance to the Small Pox vaccine, and the debunked paper by Andrew Wakefield linking vaccines to autism); Tara Haelle, *This Is the Moment the Anti-Vaccine Movement Has Been Waiting For*, *N.Y. TIMES* (Aug. 31, 2021), <https://www.nytimes.com/2021/08/31/opinion/anti-vaccine-movement.html> (discussing the growth of the anti-vaccine movement); Monica Schoch-Spana et al., *The public’s role in COVID-19 vaccination: Human-centered recommendations to*

unwilling to get the Covid-19 vaccine fall well within a long history of vaccine resistance: life restraints, perception of benefit, perception of risk, uncertainty regarding the risks the vaccine poses, lack of trust in institutions, and fear of needles.<sup>4</sup> This lack of trust in institutions is particularly interesting, with one study showing that 15% of unvaccinated individuals reported a lack of trust in institutions and another study showing that 27% of unvaccinated individuals reported a lack of trust in government.<sup>5</sup>

This mistrust in institutions has many facets. Many do not trust how quickly the vaccines were made.<sup>6</sup> Others express general misgivings with the government or large pharmaceutical companies.<sup>7</sup>

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*enhance pandemic vaccine awareness, access, and acceptance in the United States*, 39 VACCINE 6004, 6005 (2021) (discussing recent examples of high rates of American refusals to vaccinations).

4. See Benoit & Mauldin, *supra* note 3, at 2; ATA A. USLU ET AL., *Report #63: The Decision to not Get Vaccinated, from the Perspective of the Unvaccinated*, THE COVID-19 CONSORTIUM FOR UNDERSTANDING THE PUBLIC'S POLICY PREFERENCES ACROSS STATES: THE COVID STATES PROJECT: A 50-STATE COVID-19 SURVEY, at 6 (Sept. 14, 2021), <http://news.northeastern.edu/uploads/COVID19-CONSORTIUM-REPORT-63-TRUST-Sep2021.pdf>.

5. ATA A. USLU et al., *supra* note 4, at 6; Rani Molla, *Who isn't getting vaccinated, and why*, VOX (Mar. 15, 2021, 7:15 AM), <https://www.vox.com/recode/22330018/covid-vaccine-hesitancy-misinformation-carnegie-mellon-facebook-survey>.

6. See e.g., Molla, *supra* note 5 (discussing a study showing that 40% of unvaccinated individuals reasoned that they needed to wait to see if the vaccines were safe due to how quickly they were created); Jeffrey Kluger, *Too Many Americans Still Mistrust the Covid-19 Vaccines. Here's Why*, TIME (Jan. 5, 2021, 9:36 AM), <https://time.com/5925467/covid-19-vaccine-hesitancy/> (discussing vaccine hesitancy based upon how quickly the vaccines were made).

7. See e.g., Frank Newport, *COVID and Americans' Trust in Government*, GALLUP (Feb. 11, 2022), <https://news.gallup.com/opinion/polling-matters/389723/covid-americans-trust-government.aspx> (“A poll conducted by CNBC last fall concluded that unvaccinated Americans' reasons for not getting the vaccine included low trust in the federal government. Census Bureau data from December show that lack of trust in the vaccine and lack of trust in the government are among the top reasons chosen by the unvaccinated to explain their vaccine decision-making. And a 2021 poll conducted by Axios/Ipsos showed that Americans' trust in information from the government is much lower among the unvaccinated than among the vaccinated.”); Carl A. Latkin et al., *Trust in a COVID-19 vaccine in the U.S.: A social-ecological perspective*, 270 SOC. SCI. & MED., at 2 (Feb., 2021) (“A further dimension of vaccine trust is based on perceptions of vaccine makers. In the United States, pharmaceutical companies are the most poorly regarded industry . . . . This perception may be due in part to their role

Given this prevailing hesitancy much institutional focus in dispelling these misgivings has focused on educational initiatives.<sup>8</sup> But education alone cannot solve this issue. The overwhelming evidence of the vaccine's effectiveness and safety, and the educational explanations to go along with it, already exist;<sup>9</sup> yet, vaccine hesitancy has nonetheless persisted.<sup>10</sup>

Despite this crisis of vaccine skepticism and mistrust for the vaccine-production industry,<sup>11</sup> there has been little public focus on the actual laws that govern these institutions to ensure that they are engaging in safe and ethical vaccine-production. The failure to evaluate the current legal infrastructure represents a missed opportunity for identifying areas for improvement.

While some legal framework exists to govern the scientific-research industry to ensure its ethical compliance, it fails to specifically address the vaccine-manufacturing industry or provide the necessary legal mechanisms to ensure its compliance.<sup>12</sup> The National Research Act was passed by Congress in 1974, as an effort to create and impose ethical regulations on the use of human subjects in scientific research.<sup>13</sup> The Act was passed in response to the public revelations of the U.S. Public Health Service Syphilis Study at Tuskegee, whereby government researchers withheld treatment for African American men suffering

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in the ongoing opioid epidemic of exaggerating of benefits, downplaying of risks, aggressive marketing, and failure to warn the public of the addictive nature of the narcotics . . . . This well-documented role in the opioid epidemic is likely to have led to mistrust in pharmaceutical companies' ability to distribute safe and effective COVID-19 vaccines.”).

8. See e.g., *COVID-19 Educational Resources*, U.S. FOOD AND DRUG ADMIN. (Sep. 29, 2021), <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-educational-resources>; *Training and Education Resources*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Aug. 4, 2021), <https://www.cdc.gov/vaccines/covid-19/training-education/resources.html>.

9. See *id.*

10. See CTRS. FOR DISEASE CONTROL AND PREVENTION, *supra* note 2.

11. See USLU, *supra* note 4, at 6; Molla, *supra* note 5.

12. Cf. Anietie Maureen-Ann Akpan, *Dark Medicine: How the National Research Act has Failed to Address Racist Practices in Biomedical Experiments Targeting the African-American Community*, 11 SEATTLE J. FOR SOC. JUST. 1123, 1139 (Spring 2013) (according to BB, some parenthetical is strongly recommended with Cf.)

13. PL 93–348 (HR 7724), PL 93–348, 88 Stat 342 (1974).

from Syphilis in order to conduct a research study.<sup>14</sup> Notably lacking from this legislation was the creation of any criminal liability for those who violate the ethical standards promulgated pursuant to the Act.<sup>15</sup> Given the pervasive lack of trust in institutions amongst the unvaccinated population,<sup>16</sup> the lack of criminal punishments for vaccine-producers can only serve to further the beliefs of skeptics that the industry lacks accountability and cannot be trusted. Thus, one important step in mending the skepticism that exists should be strengthening the current laws governing ethical compliance by adding criminal liability.

This Essay will argue that the National Research Act should be amended to impose criminal liability and encompass all vaccine-production processes, as a means of ensuring compliance and assuring the general public of the vaccine-manufacturing industry's ethical integrity. Part I will evaluate the current legal framework and identify its shortcomings. Part II will propose a method for adding criminal liability to the legal framework. Part III will discuss how the proposed criminal liability fits well within traditional theories of common law, demonstrating that the field of vaccine-production is appropriate for criminal regulation. Ultimately, this Essay's proposal intends to help more Americans feel comfortable taking vaccines, which has been so instrumental in the fight against Covid-19 and saving lives.<sup>17</sup>

#### PART I: THE NATIONAL RESEARCH ACT'S FLAWS

The National Research Act was the first federal law aimed at protecting human subjects in medical and scientific studies.<sup>18</sup> The Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.<sup>19</sup> The Commission's main

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14. See *The U.S. Public Health Service Syphilis Study at Tuskegee*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Apr. 22, 2021), <https://www.cdc.gov/tuskegee/index.html> (containing general information regarding the Study and its implications).

15. *Id.*

16. See USLU, *supra* note 5, at 6.

17. See Kelen, *supra* note 1.

18. See Maureen-Ann Akpan, *supra* note 12, at 1139. PL 93-348 (HR 7724), PL 93-348, 88 Stat 342 (1974).

19. PL 93-348 (HR 7724), PL 93-348, 88 Stat 342 (1974).

charge was to identify and develop ethical guidelines for proper scientific research involving human subjects.<sup>20</sup> The Commission's primary product was the Belmont Report, which summarized the ethical principles that the Commission believed should serve as the guidelines imposed by Health and Human Services (HHS) going forward.<sup>21</sup> Examples of these principles included "informed consent . . . , comprehension . . . , voluntariness . . . , assessment of risks and benefits . . . , [and] selection of subjects."<sup>22</sup> The Office of Human Research, a division of HHS, was then responsible for implementing these recommendations.<sup>23</sup> In 1981, these recommendations were then imposed as regulations, and then in 1991 they were adopted by the 16 federal agencies responsible for conducting scientific research, including the National Institute of Health (NIH).<sup>24</sup> The regulations stipulate that any research receiving federal grants must certify that they are meeting general requirements set forth for each of the identified principles.<sup>25</sup> For example, the regulations list requirements for "informed consent"—a principle outlined in the Belmont report—including that the human subject be provided "a description of any reasonably foreseeable risks or discomforts to the subject" and "a description of any benefits to the subject or to others that may reasonably be expected from the research ; then, the regulations specify the procedures through which research institutions must certify they are meeting the informed consent requirements.<sup>26</sup> The National Research Act also created institutional review boards to monitor institutions involved in scientific research with human subjects and to enforce the

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20. See NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, (GPO Pub. No. 887-809, 1979). (hereafter "The Belmont Report"); PL 93-348 (HR 7724), PL 93-348, 88 Stat 342 (1974).

21. The Belmont Report, *supra* note 20, at 809.

22. *Id.*

23. See Todd W. Rice, *The Historical, Ethical, and Legal Background of Human-Subjects Research*, 53 RESPIRATORY CARE 1325, 1328-29 (2008).

24. See *id.* at 1329; Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46.101.

25. Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46.101.

26. Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46.116.

penalty for non-compliance with the regulations, which is the suspension or termination of federal funding<sup>27</sup>

Yet, many important elements of a legal framework that could constructively govern ethical compliance in science were notably lacking. First, the National Research Act only ensured ethical practices with respect to scientific and medical research involving human subjects.<sup>28</sup> The NRA was enacted primarily to address the wrongs of the Tuskegee study, and thus its limited scope was intended to solely ensure such wrongs did not occur again.<sup>29</sup> Yet with hindsight, the NRA could have been expanded to encompass other forms of research beyond that which involves human subjects, specifically vaccine production and research.<sup>30</sup> Second, the NRA lacked any provisions for criminal liability in the event that the ethical guidelines identified by the Belmont Commission were violated.<sup>31</sup> Even at the time of the Act's passage, the lack of criminal liability was a clear failure to take advantage of the full legislative options available to lawmakers.<sup>32</sup> As such, the combined lack of coverage for other forms of research and any criminal liability fell short of creating a comprehensive legal framework.

## PART II: HOW CRIMINAL LIABILITY COULD BE IMPOSED

To successfully develop criminal penalties for ethical breaches in vaccine production, the production process will first need to be studied to identify what the most effective laws would be. Despite its failure to go beyond regulatory penalties, the NRA provides a cohesive model for how we could develop and implement criminal laws to ensure that vaccine research and production comply with proper ethical standards. Just as the NRA was motivated by the distrust of the research

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27. See Rice, *supra* note 21, at 1329; Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46.108.

28. PL 93-348 (HR 7724), PL 93-348, 88 Stat 342 (1974).

29. See Akpan, *supra* note 18, at 1135-8; PL 93-348 (HR 7724), PL 93-348, 88 Stat 342 (1974).

30. See PL 93-348 (HR 7724), PL 93-348, 88 Stat 342 (1974).

31. See Akpan, *supra* note 18, at 1146-7, 1139; PL 93-348 (HR 7724), PL 93-348, 88 Stat 342 (1974) [[See Rule 12]]. The legislative history also shows no consideration of criminal liability. See H.R. CONF. REP. 93-1148; S. REP. 93-381.

32. See Akpan, *supra* note 18, at 1141-52.

industry following the Tuskegee Study,<sup>33</sup> the new legislation would similarly be motivated by the distrust of the vaccine-manufacturing industry brought to light by those hesitant to receive the Covid-19 vaccine.<sup>34</sup> The new legislation would copy the NRA's by creating of a commission tasked with identifying the necessary guidelines for safe and ethical vaccine research and manufacturing.<sup>35</sup> As with the Belmont Report, the commission's findings would not be mere "recommendations," but would rather create the actual regulations in full that would then be implemented.<sup>36</sup> Thus, the new commission's report will be an essential element of the new legislation's infrastructure.

The guidance for the commission's new guidelines would be two-fold: first, further studying the precise factors driving vaccine skepticism; second, building upon current regulations. To achieve its objective of creating confidence and comfort with vaccines among those currently hesitant to receive the Covid-19 vaccine, the new commission first needs to identify what specifically is driving these hesitations. Presently, studies have been conducted since the creation of the Covid-19 vaccine to understand the reasoning of the vaccine-skeptical population.<sup>37</sup> However, these studies only scratch the surface of understanding the precise causes of this skepticism.<sup>38</sup> They

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33. See CTRS. FOR DISEASE CONTROL AND PREVENTION, *supra* note 13.

34. This proposed similarity is not meant to suggest an equivalency between the Tuskegee Study and the process by which the Covid-19 vaccines were researched and manufactured. Rather, the similarity merely exists in the distrust within particular communities that resulted from each event. Just as with the NRA, the proposed legislation aims to dissuade such mistrust.

35. PL 93-348 (HR 7724), PL 93-348, 88 Stat 342 (1974).

36. NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, (GPO Pub. No. 887-809, 1979).

37. See USLU *supra* note 4, at 4.

38. See MAYA J. GOLDENBERG, VACCINE HESITANCY: PUBLIC TRUST, EXPERTISE, AND THE WAR ON SCIENCE 111 (2021) ("While it is not uncommon to hear that vaccine hesitancy and vaccine uptake result from poor public trust...it is uncommon for the implications of this widely accepted claimed to be rigorously studied. In broad discussions of vaccine hesitancy, poor trust typically appears on the laundry lists of the multiple causes of this phenomenon. But this finding does not get carried into strategies for addressing the problem...The empirical research into trust and vaccines is limited in both quantity and quality.").

successfully identify the broad motives of the skeptical population,<sup>39</sup> but fail to frame these motives with specificity. Knowing that skeptics proclaim mistrust in government or the pharmaceutical industry broadly, or that skepticism exists in higher levels in the Black community, is certainly helpful.<sup>40</sup> However, successfully developing laws that will help assuage such skepticism will require understanding the specific reasons motivating the skepticism. Thus, this new commission will need to undertake studies to gather more extensive evidence for understanding what motivates skeptics.

Additionally, the new commission will build upon current regulations that govern research ethics in other fields within the scientific community to create effective regulations for ethical and safe vaccine production. In large part, these regulations exist as a result of the NRA.<sup>41</sup> For example, current regulations extensively identify and define each element of the research process.<sup>42</sup> They can also provide some guidance for setting up monitoring systems and enforcing compliance with the new laws.<sup>43</sup> Therefore, the commission will have an extensive basis on which to design laws which sufficiently assure ethical vaccine production, based upon current regulations regarding ethical scientific research. To be sure, the commission will also have the capability to charter new studies to access more information if needed. Therefore, the dual sources of guidance for the commission's work aim to guarantee that their designed laws both generate public confidence in vaccines and require ethical scientific research.

### PART III: THE ARGUMENT FOR CRIMINAL LIABILITY LEADING TO INCREASED TRUST IN VACCINES

Criminal liability will add an important monitor within the production industry to further ensure accountability. This correlation has two primary elements: first, criminal law functions as a public

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39. *See generally* USLU *supra* note 4.

40. *Id.*

41. *See Rice supra* note 23, at 1328.

42. Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46.102.

43. Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46.103 (containing provisions detailing how scientific institutions can certify their ethical compliance and how the institutional review boards can verify the legitimacy of these certifications).



condemnation of the proscribed crime;<sup>44</sup> second, the threat of criminal punishments provides a necessary deterrent to ensure ethical compliance.<sup>45</sup>

Criminal law delivers a heightened perception of individual and communal safety that cannot be achieved solely through civil liability. Almost all theories of criminal law deem delivering justified punishment to be one of, if not the main, function of criminal law.<sup>46</sup> Such criminal punishment has further reach than a comparable civil penalty could have; the distinction between each form of liability is that “the essence of punishment for moral delinquency lies in the criminal conviction itself . . . it is the expression of the community’s hatred, fear, or contempt for the convict which alone characterizes physical hardship as punishment.”<sup>47</sup> Essentially, a key purpose of the criminal law and its imposition of imprisonment is to send a message that civil law cannot. It communicates to both the offender and society at-large that the conduct in question is deserving of the highest societal condemnation. Thus, imposing criminal liability on vaccine-producers will send the message to society at-large that ethical breaches within the vaccine-production industry are taken seriously.<sup>48</sup> Contrastingly, the failure to include criminal liability for unethical vaccine-production processes sends a message that society values the harm of such ethical violations

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44. See e.g., George K. Gardner, *Richardson and the Constitution of the United States*, 33 B.U. L. REV. 176, 193 (1953); *Missouri v. Hunter*, 459 U.S. 359, 373 (1983) (J. Marshall, dissenting) (“[E]ach criminal conviction itself represents a pronouncement by the State that the defendant has engaged in conduct warranting the moral condemnation of the community.”).

45. See Crump, *infra note* 50, at 320.

46. See e.g., Paul H. Robinson, *Criminal Law’s Core Principles*, 14 WASH. U. JURIS. REV. 153, 164 (2021) (discussing the “fundamental shared belief that blameworthy wrongdoing deserves punishment”).

47. George K. Gardner, *Richardson and the Constitution of the United States*, 33 B.U. L. REV. 176, 193 (1953).

48. Taking these breaches seriously is key to building trust. For example, one prominent group in Texas opposing the Covid-vaccine stated that “it is also our position that the fast-track designation of the vaccine which began human trials today is cause for concern, as essential steps in the safety assessment process will not be undertaken before administering the vaccine to healthy individuals.” Brittny Martin, *Texas Anti-Vaxxers Fear Mandatory COVID-19 Vaccines More Than the Virus Itself*, TEXAS MONTHLY (Mar. 18, 2020), <https://www.texasmonthly.com/news-politics/texas-anti-vaxxers-fear-mandatory-coronavirus-vaccines/>.

less than the harm of other ethical violations typically deemed as crimes, such as assault or robbery.<sup>49</sup>

Furthermore, under the traditional deterrent view of criminal law, criminal laws aim to create a disincentive to commit the proscribed criminal conduct, such that the criminal activity occurs significantly less.<sup>50</sup> Deterrence theory is well-entrenched within criminal law.<sup>51</sup> For example, the U.S. Sentencing Guidelines, which are intended to “assure the ends of justice,”<sup>52</sup> list “deterrence” as one of the basic purposes of criminal law.<sup>53</sup> Additionally, another purpose of the Sentencing Guidelines is that “general deterrence of criminal conduct dictates that a clear message be sent to society that repeated criminal behavior will aggravate the need for punishment with each occurrence.”<sup>54</sup> The proposed criminal liability for those involved in vaccine production will fit this pattern. The threat of criminal punishments makes the cost of unethical behavior for vaccine-producers too high. In short, the deterrent element of criminal laws influences the greater community as well, sending a message that the proscribed crime is being deterred

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49. See generally Robinson, *supra* note 42, at 182–87 (discussing the principle that “relatively more serious offenses are deserving of relatively greater punishment”).

50. See e.g., David Crump, *Deterrence*, 49 ST. MARY'S L.J. 317, 320 (2018) (“By this theory, the more certainty there is in detection, apprehension, conviction, and sentence, the greater the deterrent. The logic behind the conjecture is that a high probability of punishment is a determinant of the cost of committing the contemplated crime.”); CESARE BECCARIA, ON CRIMES AND PUNISHMENTS (David Young trans., 1986) (1764), as reprinted in DAVID CRUMP ET AL., CRIMINAL LAW CASES, MATERIALS, AND LAWYERING STRATEGIES 558 (3d ed. 2013) (“The purpose of punishment, then, is nothing other than to dissuade the criminal from doing fresh harm to his compatriots and to keep other people from doing the same . . . . Therefore, punishments and the method of inflicting them should be chosen that, mindful of the proportion between crime and punishment, will make the most effective . . . impression on [people's] minds.”).

51. See Kelli D. Tomlinson, *An Examination of Deterrence Theory: Where Do We Stand?*, 80 FED. PROB. 33, 33 (2016) (“Deterrence theory has been the underlying foundation for many criminal justice policies and practices throughout the course of American history.”); see generally Athula Pathinayake, *Contextualizing Specific Deterrence in an Era of Mass Incarceration*, 18 CONN. PUB. INT. L.J. 357, 359–62 (2019) (discussing the prevalence of deterrence theory in American criminal law historically).

52. U.S. SENT’G GUIDELINES MANUAL ch. 1, pt. A, introduction. (U.S. Sent’g Comm’n Nov. 2021).

53. *Id.*

54. *Id.*, at ch. 4, pt. A, introduction.

against, which in turn may lead to a greater sense of safety. Given how much of the hesitancy was driven by a perceived lack of safety in the Covid-19 vaccine-production process,<sup>55</sup> implementing measures such as these to increase confidence in the safety of vaccines is critical to fighting vaccine hesitancy.

Criminal liability directly addresses the mistrust and lack of accountability perceived by vaccine skeptics. A strong correlation exists between the unvaccinated population and mistrust in government, as well as mistrust in the pharmaceutical industry.<sup>56</sup> The relationship between trust and vaccination is in many ways natural. The general public lacks the scientific expertise necessary to possibly check the work of the scientists involved in the production of vaccines and are, thus, left solely to trust in the integrity and honesty of the work of scientific experts.<sup>57</sup> Therefore, measures which increase confidence in the integrity and honesty of the work of the vaccine-production process will be integral to increasing trust in vaccines. Criminal punishments represent a condemnation by all of society towards the wrongdoer for committing the regulated crime.<sup>58</sup> The possibility for such a condemnation communicates to vaccine skeptics that society is taking the possibility of ethical malfeasance seriously, which in turn may serve to assuage their current skepticism. Likewise, as society believes criminal laws deter the proscribed criminal conduct,<sup>59</sup> the implementation of criminal liability will then lead society to perceive

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55. See generally USLU, *supra* note 4.

56. See Newport, *supra* note 7.

57. See generally MAYA J. GOLDENBERG, VACCINE HESITANCY: PUBLIC TRUST, EXPERTISE, AND THE WAR ON SCIENCE 12425 (2021) (“[T]he rationality of following expert advice hinges on trust and credibility: experts must be trustworthy and nonexperts must recognize them as such. Relations of trust mediate successful exchanges between scientific institutions and the publics. The publics need additional trust beyond confidence in the epistemic and moral integrity of the individual expert; trust is also needed in the integrity of expert institutions to work in the publics’ interest rather than in the furtherance of alternate agendas that are oppressive or unjust. Public trust in science demands socially responsible science that is transparent about the interests it serves and aware of its own histories of power and privilege.”).

58. See *Missouri v. Hunter*, 459 U.S. 359, 373 (1983) (J. Marshall, dissenting) (“[E]ach criminal conviction itself represents a pronouncement by the State that the defendant has engaged in conduct warranting the moral condemnation of the community.”).

59. See Crump, *supra* note 50.

increased adherence to ethical vaccine-practice. In short, society may believe that those producing vaccines have significant incentives, which do not exist currently, to comply with ethical requirements. Thus, criminal liability can help provide the increased trust necessary to assuage the unvaccinated population's skepticism to then persuade unvaccinated individuals to receive future vaccinations.

#### PART V: BRIEFLY REFUTING A CHALLENGE TO THE NECESSITY OF CRIMINAL LIABILITY

Legislators may question the necessity of criminal liability because the vaccine-industry is already ethically compliant.<sup>60</sup> This challenge misses the point that criminal laws can also function as a message from society at-large; as Justice Marshall wrote, “each criminal conviction itself represents a pronouncement by the State that the defendant has engaged in conduct warranting the moral condemnation of the community.”<sup>61</sup> To be sure, vaccines have already proven to be safe and effective,<sup>62</sup> thus begging the question of whether the proposed criminal laws will result in any sizeable number of prosecutions. But the proposed laws have another goal—to increase confidence in vaccines and lead to higher rates of vaccination. Adding criminal punishment does just that, by sending the message that ensuring ethical behavior in the vaccine-industry is taken just as seriously as ensuring ethical behavior in other forms of social conduct that are typically regulated with criminal punishments. Therefore, the mere existence of the criminal laws regulating the production industry is the intended goal, and whether any significant number of actual prosecutions result is immaterial to that goal.

#### CONCLUSION

Vaccine skepticism poses a major threat to American public health. A consistently sizeable portion of the American public

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60. See e.g., *Developing COVID-19 Vaccines*, CDC (Feb. 4, 2022), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/distributing/steps-ensure-safety.html> (discussing the step-by-step process through which the Covid-vaccines were made and how each step complied with current ethical standards).

61. Hunter, 459 U.S. at 373 (1983).

62. See *Kelen*, *supra* note 1.

remaining skeptical to vaccinations is a societal issue in need of a significant remedy going forward. Building trust for the vaccine-production industry, as well as confidence in the integrity of the members of the industry, is essential to reducing vaccine skepticism. The current mainstream actions to reduce vaccine skepticism focus overwhelmingly on educational methods.<sup>63</sup> Education is critical, but implementing criminal liability should also play an important role in addressing the mistrust and perceived lack of accountability within the vaccine-production industry. The threat of criminal liability provides the incentives necessary within the industry that allows the wider population to perceive that the industry is acting ethically and with integrity in the production of vaccines. Furthermore, society is used to seeing the criminal law as the most effective means to ensuring public safety; and therefore, implementing criminal liability is a necessary means for society to perceive ethical compliance within vaccine production. Through such a perception, the skeptical community can begin to feel safe with the production process.

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63. See U.S. FOOD AND DRUG ADMIN., *supra* note 8.