LOOKING TOWARD BREXIT'S AFTERMATH: PHARMACEUTICAL PROVISIONS AFFECTING THE NHS IN A FUTURE U.S.-U.K. BILATERAL TRADE AGREEMENT

By Ryan Rainey[1]

Introduction

Among the United Kingdom's citizens, "[n]othing inspires national pride quite like the National Health Service."[2] Still, Britain's political class is attempting to wade through a difficult time for the NHS, a "single-payer" national health system which is facing increased budgetary and administrative challenges.[3] In 2017 alone, the U.K. government spent over £140 billion – or $180 billion – on the NHS.[4] The NHS has experienced numerous domestic challenges related to the U.K.'s aging population, combined with budgetary growth, since its 1956 enactment.[5] This has led to a search for novel solutions to ensure its long-term financial sustainability, including through external policy. Proponents of the U.K.'s departure from the European Union, or "Brexit," argued that leaving the union would allow Parliament

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2. Pamela Duncan & Juliette Jowit, *Is the NHS the World's Best Healthcare System?*, GUARDIAN (July 2, 2018), https://www.theguardian.com/society/2018/jul/02/is-the-nhs-the-worlds-best-healthcare-system.

3. *See* Nick Triggle, *10 Charts That Show Why the NHS Is in Trouble*, BBC NEWS (May 24, 2018), https://www.bbc.com/news/health-42572110. Overall government spending on the NHS has increased, while the share of national government spending on health care has tripled as a percentage of the public services budget since the NHS' implementation in the 1950s. Moreover, NHS customers have faced longer wait times for emergency services at NHS hospitals, *id.*

4. *Id.*

5. *Id.*

to reinvest in the NHS.[6] Meanwhile, Conservative politicians seeking to move beyond Brexit have pledged to reassert Britain's position on the global stage by negotiating a standalone free trade agreement ("FTA") with the country's closest ally, the United States.[7] But U.S. officials' comments about the connection between the NHS and a trade deal — especially those related to the NHS' pharmaceutical procurement regime — have made the British public skittish.[8]

The debate over the NHS and its possible linkage to a trade agreement could have significant importance for the leaders of both countries. For Former President Donald Trump, the discussions presented an opportunity to claim a victory for major U.S. industries like pharmaceuticals in a tough-to-penetrate foreign market – especially at a time where his trade policy toward China has become a major political controversy.[9] For Prime Minister Boris Johnson and his Conservative government, the talks are a similarly important way to reassert the Tories' commitment to the NHS while balancing the U.K.'s post-Brexit stature on the international stage. For U.K. citizens, the talks could determine issues of consequence including the availability and cost of important medicines and the program's administrative efficiency.

In this note, I will describe the legal basis and mechanisms available to both the supporters and opponents of opening the NHS up to more participation from foreign pharmaceutical companies through a U.S. trade deal. First, I will describe the

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6. *See* Stephen Castle, *Having Won, Some 'Brexit' Campaigners Begin Backpedaling*, N.Y. TIMES (June 26, 2016), https://www.nytimes.com/2016/06/27/world/europe/having-won-some-brexit-campaigners-begin-backpedaling.html ("Boris Johnson, the former mayor of London who was the frontman of the Brexit campaign, toured Britain in a bus emblazoned with the slogan: 'We send the E.U. £350 million a week, let's fund our N.H.S. instead,' a reference to the country's widely revered National Health Service.").

7. Julian Borger, *US Will Be 'on Doorstep' Ready to Sign UK Trade Deal After Brexit, Says Pompeo*, GUARDIAN (Aug. 7, 2019), https://www.theguardian.com/us-news/2019/aug/07/us-uk-trade-deal-mike-pompeo-brexit-dominic-raab (reporting U.K. foreign secretary Dominic Raab's comments).

8. *See* Antony Barnett, *My Investigation into a US Trade Deal Shows It Really Could Cost the NHS Millions*, GUARDIAN (Nov. 27, 2019), https://www.theguardian.com/commentisfree/2019/nov/27/us-trade-deal-nhs-investigation-brexit-drugs.

9. Demetri Sevastopulo & Colby Smith, *Trump Plays Down Fallout from China Trade War*, FIN. TIMES (Aug. 7, 2019), https://www.ft.com/content/7afb85da-b858-11e9-96bd-8e884d3ea203.

investment and intellectual property provisions the U.S. has negotiated in previous trade agreements, and how they could be relevant to U.S.-U.K. discussions over the NHS. Second, I will analyze how specific provisions in U.S. trade agreements have dealt with national health programs similar to the NHS. Third, I will describe how investment provisions could allow U.S. companies to challenge the U.K.'s compliance with provisions involving the NHS, and evaluate potential compromises negotiators could make to assuage concerns on both sides of the debate. Finally, I will assess the likelihood of such major legal changes in the current political context, and how non-binding legal solutions could provide similar outcomes without the severity of compulsory language.

I. Background

A. NHS and U.K.-U.S. Trade Negotiations

After a years-long political battle over a Brexit strategy, the Conservative Party won a decisive election in December 2019 which allowed them to take a large majority in the House of Commons.[10] The U.K. formally left the EU in early 2020.[11] Johnson also described NHS changes as a "top priority" for his new government[12] after taking campaign attacks from the opposition Labour Party over the Conservative government's handling of the NHS.[13] Labour replaced Jeremy Corbyn, its leader in the unsuccessful campaign against Johnson, with Keir Starmer in April 2020.[14]

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10. *See* Cristina Gallardo, *What Boris Johnson's Victory Means for Brexit*, POLITICO (Dec. 13, 2019), https://www.politico.eu/article/uk-general-election-2019-what-boris-johnsons-victory-means-for-brexit/ (reporting that the Conservatives took the majority in a December 12 election for which Brexit was the primary issue at stake).

11. *Brexit: The UK Has Officially Left the EU — What Happens Next?*, BBC NEWS (Jan. 31, 2020), https://www.bbc.com/news/world-europe-51307874.

12. Rowena Mason & Kate Proctor, *Boris Johnson Pledges to Prioritize NHS After Election Victory*, GUARDIAN (Dec. 13, 2019), https://www.theguardian.com/politics/2019/dec/13/boris-johnson-pledges-to-prioritise-nhs-after-election-victory.

13. Denis Staunton, *Conservatives Criticised by Labour over Poor NHS Performance*, IRISH TIMES (Nov. 14, 2019), https://www.irishtimes.com/news/world/uk/conservatives-criticised-by-labour-over-poor-nhs-performance-1.4083399.

14. *Labour Leadership Winner: Sir Keir Starmer*, BBC NEWS (Apr. 4, 2020), https://www.bbc.com/news/uk-politics-51049756.

The 2020 COVID-19 pandemic represents an unexpected event which will likely bring into contrast the political differences between Conservatives, Labour and other U.K. political parties of significance. Austerity measures that Conservative governments enacted in the aftermath of the 2008 financial crisis put further financial strain on the NHS.[15] These decisions could become more politically controversial in the aftermath of the coronavirus crisis, since opponents of the austerity measures are likely to argue that the financial limitations restricted the NHS' ability to prepare for the pandemic.[16] Amid the pandemic, the new Labour leader Starmer argued that further austerity as a general principle would be an inappropriate policy response, and that the NHS' funding structure would need an overhaul that requires more revenue from wealthy Britons.[17]

Brexit, COVID-19, and the NHS' troubles all coincide with perhaps the main external policy issue facing Johnson's government: the prospect of negotiating a standalone free trade agreement with the United States.[18] Johnson and Trump are, in some ways, ideological kindred spirits who both favor Brexit and have similar political bases.[19] However, the political sensitivity of the NHS has led to skepticism that Johnson would allow the U.S. to exploit trade negotiations to satiate the U.S. health care

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15. Mark Landler & Stephen Castle, *On Job Just 6 Weeks, U.K.'s Finance Chief Shines in Crisis*, N.Y. TIMES (Mar. 26, 2020), https://www.nytimes.com/2020/03/26/world/europe/coronavirus-uk-rishi-sunak.html.

16. *Id.* As of this Note's submission, center-left and left-wing commentators were strongly warning against implementing deficit-limiting austerity measures to address the COVID-19 crisis, amid increased calls for investment in major public health infrastructure like the NHS. *See* Donna Ferguson, *Only 12% Want a Return to the Old 'Normal' Britain After Covid-19*, OBSERVER (July 12, 2020), https://www.theguardian.com/world/2020/jul/12/only-12-want-a-return-to-the-old-normal-britain-after-covid-19.

17. *See Coronavirus: Key Workers 'Overlooked and Underpaid', Says Starmer*, BBC NEWS (Apr. 5, 2020), https://www.bbc.com/news/uk-52169648.

18. *See* Clark Packard, *Trump and Johnson Can Quickly Strike a Trade Deal—If They Avoid the Pitfalls*, FOREIGN POL'Y (Mar. 11, 2020), https://foreignpolicy.com/2020/03/11/trump-johnson-us-britain-trade-agreement-fta ("In the coming months, the United Kingdom will begin negotiating a free trade agreement (FTA) with its most important trading partner other than the EU: the United States.").

19. *See* Daniel Lippman & Nahal Toosi, *Boris and Donald: A Very Special Relationship*, POLITICO (Dec. 13, 2019), https://www.politico.com/news/2019/12/12/trump-boris-johnson-relationship-083732.

industry's appetite for more access to the U.K.'s market.[20] Discussions toward formal negotiations got off to an inauspicious start when U.S. President Donald Trump suggested that the NHS would be "on the table" in bilateral talks, before walking those comments back during Johnson's December campaign.[21] Johnson also attempted to reassure voters of the NHS' sacrosanct nature in the Tories' election manifesto.[22] Formal talks have not yet begun, but U.S. officials are still pushing for negotiations publicly amid the pandemic.[23]

Despite Trump's walk-back, language remains in the U.S.' key negotiating objectives calling for "standards to ensure that government regulatory reimbursement regimes are transparent, provide procedural fairness, are nondiscriminatory, and provide full market access for U.S. products."[24] This language likely reflects input from pharmaceutical industry stakeholders, who have long had a role in shaping U.S. free trade agreements negotiated under both Republican and Democratic presidents.[25] Notably, pharmaceutical industry executives sit on the formal advisory committee that counsels U.S. government negotiators on sectoral priorities during negotiations.[26] These committees,

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20. *See* Alexander Smith, *NHS: Specter of U.S. Interference Looms over Health Care Debate in U.K.*, NBC NEWS (Dec. 5, 2019), https://www.nbcnews.com/news/world/nhs-specter-u-s-interference-looms-over-health-care-debate-n1082121 ("[T]he opposition Labour Party is raising concerns that another Conservative government could 'sell off' the NHS to the United States.").

21. Sarah Neville, *Could the NHS Be Part of a US-UK Trade Deal?*, FIN. TIMES (June 5, 2019), https://www.ft.com/content/7795cb64-877d-11e9-97ea-05ac2431f453; *see also General Election 2019: Trump Wants 'Nothing to Do' with NHS in Trade Talks*, BBC NEWS (Dec. 3, 2019), https://www.bbc.com/news/election-2019-50638110 [hereinafter *General Election 2019*] (quoting Trump's assertion that he "[didn't] even know where that rumour started," and that the U.S. would want "nothing to do" with the NHS in trade talks).

22. *See General Election 2019*, *supra* note 21.

23. *USTR: 'Active' Trade Talks with the UK to Begin in the Near Future*, INSIDE U.S. TRADE (Apr. 9, 2020), https://insidetrade.com/daily-news/ustr-%E2%80%98active%E2%80%99-trade-talks-uk-begin-near-future.

24. OFFICE OF THE U.S. TRADE REPRESENTATIVE, EXEC. OFFICE OF THE PRESIDENT, UNITED STATES-UNITED KINGDOM NEGOTIATIONS, SUMMARY OF SPECIFIC NEGOTIATING OBJECTIVES (2019) [hereinafter USTR NEGOTIATING OBJECTIVES].

25. *See generally infra* Sections II.A, II.B, and II.C.

26. Notice of Continuation and Request for Nominations for the Industry Trade Advisory Committees, 83 Fed. Reg. 21,813–14 (May 10, 2018). ITAC 3 advises the administration on chemicals, pharmaceuticals, and health/science products and services, *id.*

known as Industry Trade Advisory Committees ("ITACs") are composed of "members with experience relevant to the industry sector."[27] ITACs submit stakeholder reports on the provisions of finalized trade agreements; after the Trans-Pacific Partnership negotiations, members of the committee included executives from Eli Lilly & Co., Amgen Inc., and Dow Chemical Co.[28]

These specific negotiating objectives, which are non-binding and form a roadmap of sorts for future negotiations, have been among the most contentious of the goals the Office of the U.S. Trade Representative ("USTR") announced.[29] One U.K. civil society group, the NHS Confederation, argues that the USTR negotiating objectives appear to refer to the NHS' pharmaceutical pricing and access scheme, known as VPAS, which is slated to expire at the end of 2023.[30] VPAS caps the NHS' spending on brand-name drugs in an effort to ensure "predictability of expenditure for the NHS" for all branded pharmaceuticals.[31] By seeking greater, "nondiscriminatory" market access for U.S. firms, the more patentholder-friendly IP requirements would attach in the U.K. in the wake of a trade agreement's enactment.[32]

B. ISDS, Property Rights, and Carveouts

One of the most pressing public concerns regarding the NHS and a U.S.-U.K. trade agreement involves the potential use of intellectual property protections and the investor-state dispute settlement ("ISDS") process to undermine public health measures the NHS undertakes. This concern is especially relevant in the context of IP measures, which vary significantly from country to country and can influence the prices of the drugs and medical devices that services like the NHS purchase.[33] The USTR Negotiating Objectives also raise more general, non-IP

27. *Id.* at 21,814.

28. THE TRANS-PACIFIC PARTNERSHIP TRADE AGREEMENT, REPORT OF THE INDUSTRY TRADE ADVISORY COMMITTEE FOR CHEMICALS, PHARMACEUTICALS, HEALTH/SCIENCE PRODUCTS AND SERVICES 15 (2015).

29. *See* Neville, *supra* note 21.

30. NHS CONFEDERATION, THE NHS AND FUTURE FREE TRADE AGREEMENTS 9 (2019).

31. *Id.*

32. *Id.*

33. *See generally* WORLD TRADE ORG., PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE 260 (2d ed. 2020).

issues which could be relevant to the public-private partnerships which form part of the NHS' structure.[34]

The ISDS regime, simply described, allows corporations domiciled in a party to a free trade agreement to bring an arbitration action against a state's government for non-compliance with the FTA's provisions.[35] The mechanism has become an increasingly popular demand of U.S. trade negotiators, to the point where trade experts and industry groups believe that any FTA without such a provision would "get laughed off stage."[36] At the same time, it has become a matter of political controversy, especially with liberal U.S. politicians who see it as a giveaway to U.S. corporations which could use ISDS as leverage to influence the policymaking decisions of other countries with which the U.S. has an agreement.[37]

Some of the most contentious ISDS litigation has involved a U.S. company's challenge of another country's regulatory, legislative or even judicial decision as the expropriation of intellectual property.[38] For example, the U.S.-based pharmaceutical company Eli Lilly took on the Canadian judiciary's cancellation of certain intellectual property provisions through the ISDS process allowed under the North American Free Trade Agreement ("NAFTA").[39] Even if they are not successful — and Eli Lilly's ultimately was not — such actions could have a "chilling effect" on other countries' regulatory actions, including those aimed at protecting public health.[40]

Pharmaceutical companies would likely face adverse consequences from the elimination or curtailment of ISDS, since the renewal of varied patents of medicines which are about to expire (also known as "evergreening") has become a key element of the industry model.[41] However, the actual social value of evergreening is suspect, since evergreened drugs frequently

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34. *See generally* NORTON ROSE FULBRIGHT, UK-US TRADE NEGOTIATIONS: AN ANALYSIS OF THE NEGOTIATING OBJECTIVES (2020).

35. *See* HALEY SWEETLAND EDWARDS, SHADOW COURTS: THE TRIBUNALS THAT RULE GLOBAL TRADE 14–16 (2016).

36. *Id.* at 20.

37. *See id.*

38. *See id.* at 72.

39. Cynthia M. Ho, *Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions*, 30 BERKELEY TECH. L.J. 213, 215–16 (2015).

40. *Id.* at 216.

41. *Id.* at 217.

"offer no significant improvement" and could impose unfair costs on countries running already expensive national health systems.[42] Additionally, doctors and patients are often unaware of the legal developments that underpin the evergreening process, which makes the ability to determine if a brand-name drug is appropriate more difficult.[43] Overall, because of the brand-name industry's reliance on evergreening, company challenges of domestic policy decisions under foreign trade agreements have been on an upward trend, and challenges not just associated with patents but any regulatory decision are emerging for any case that "negatively [impacts] their ability to sell even patented drugs."[44] International law firms have even taken advantage of the ISDS mechanism's expansion into pharmaceutical issues and have called into question whether certain developing countries have a right to regulate on specific IP matters if they have an investment agreement with the U.S.[45]

The *Eli Lilly* arbitral panel never addressed the critical issues of national sovereignty the case raised, and instead limited its judgment to a fact-specific decision.[46] The lack of clarity on this issue could allow pharmaceutical firms to bring claims aimed at preserving the IP status quo in the face of potential changes, or to "impugn rules that better address consumer interests, including access to more affordable medicines".[47] Beyond the possibility of future panel rulings that uphold challenges to domestic regulations or judicial decisions, the ISDS mechanism could also preempt the enactment of the regulations themselves.[48] Such an outcome could nullify the legal flexibilities enshrined in the WTO-administered international rules, known as the TRIPS Agreement, that outline minimum standards for IP protection across member countries with wide differences in IP enforcement.[49] All of these issues are relevant to the NHS' pharmaceutical reimbursement

42. *Id.* at 217–18.

43. *Id.* at 218.

44. *Id.* at 222.

45. *Id.* at 250.

46. Brook K. Baker & Katrina Geddes, *The Incredible Shrinking Victory:* Eli Lilly v. Canada, *Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS*, 49 LOY. U. CHI. L.J. 479, 501 (2017).

47. *Id.* at 502.

48. *See id.* at 503.

49. *See id.*; *see also Overview: the TRIPS Agreement*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Jan. 4, 2020).

scheme, which resembles the national health systems in other FTA-party developed countries like Canada and Australia.[50]

Because of ISDS' controversy, countries have attempted to protect their right to regulate by including so-called "carveout" provisions.[51] Most notably, the public health carveouts have attempted to preserve a country's ability to take tobacco control efforts without worrying about ISDS retribution from U.S. tobacco companies.[52] Section II.C will explore the potential NHS-related carveouts.

II. Analysis

The United States has previously negotiated bilateral trade agreements with major developed economies that manage national health care systems. In particular, the successful talks with Australia and South Korea led to substantive changes to those countries' health systems, while unsuccessful talks for the Trans-Pacific Partnership ("TPP") and the Transatlantic Trade and Investment Partnership ("TTIP") would have made changes to some national health laws as well. This section will evaluate how effective these provisions have been in bilateral as well as multilateral trade agreements, and the extent to which previous solutions could show a path forward for U.S.-U.K. negotiations.

A. Australia-U.S. Trading Relationship

One of the first post-TRIPS standalone agreements the U.S. negotiated was its 2004 agreement with Australia (now known commonly as AUSFTA).[53] Early in those talks, both U.S. and Australian pharmaceutical companies viewed the negotiations as a possible means of bringing in new rules on Australia's

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50. *See, e.g.,* Alison Giest, *Interpreting Public Interest Provisions in International Investment Treaties*, 18 CHI. J. INT'L L. 321, 345 n.170 (2017) (citing to the Trans-Pacific Partnership's text that includes a reimbursement scheme).

51. *See id.* at 343 (describing "right to regulate" provisions in Trans-Pacific Partnership draft text which protected parties from ISDS litigation over regulation for "environmental protection, public welfare, public morals" or the maintenance of healthcare systems).

52. Peter K. Yu, *The Investment-Related Aspects of Intellectual Property Rights*, 66 AM. U. L. REV. 829, 867 (2017).

53. *See* Stephen R. Tully, *Free Trade Agreements with the United States: 8 Lessons for Prospective Parties from Australia's Experience*, 5 BRIT. J. AM. LEGAL STUD. 395, 397 (2016).

Pharmaceutical Benefits Scheme ("PBS").[54] At that time, the pharmaceutical stakeholders considered the PBS a non-tariff barrier to trade between the two nations.[55]

Put simply, the PBS system puts downward pressure on drug prices for Australian citizens by subsidizing the end-use costs.[56] This limits pharmaceutical manufacturers' rights to charge higher prices for brand-name drugs in the Australian market, which they see as a non-tariff barrier because of the perceived disincentive to profit off their research and innovation.[57] PBS supporters, however, argued that U.S. states themselves could enact a scheme resembling the PBS, and that making major changes through a trade agreement would result in a significant transfer of wealth to the large pharmaceutical companies.[58]

The U.S.' main AUSFTA negotiating objective involved bringing more "transparency" to the PBS regime by making it more apparent when specific drugs would come within the PBS' net.[59] Ultimately, the two countries agreed on non-binding language in which they both committed to "the need to recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical."[60] The industry applauded this language, as well as USTR's public announcement that Australia had committed to improve the PBS' administration and transparency by setting up an independent process to determine PBS qualifications.[61]

According to one Australian commentator, the AUSFTA's

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54. *Id.* at 406.

55. *Id.*

56. *See id.*

57. *Id.* ("The PBS limits the freedom of drug manufacturers to charge whatever the market will bear and does not allow them to recoup investment in research. Consumers are accessing innovative medicines without contributing substantively to their cost.").

58. *Id.*

59. *Id.*

60. *Id.* at 407.

61. *Id.* (noting that the Australian government seemed to downplay the AUSFTA's effect on the PBS by emphasizing the nonbinding nature of the language and reassuring Australians that the PBS' fundamental administration "remains intact"); *see* United States–Australia Free Trade Agreement, U.S.-Aus., May 18, 2004 118 Stat. 919 (Aug. 3, 2004); *see also* UNITED STATES TRADE REPRESENTATIVE, SUMMARY OF THE U.S.-AUSTRALIA FREE TRADE AGREEMENT, FREE TRADE "DOWN UNDER" (Feb. 8, 2004).

effect on the PBS was largely symbolic because it moved intellectual property protection into a matter of external policy.[62] The result was not to raise pharmaceutical prices for Australian consumers, but instead to "shift the balance of power from Australia to the pharmaceutical industry" in future trade negotiations.[63] This was the contemporary legal assessment in the immediate aftermath of AUSFTA's finalization; another commentator argued in 2005 that the agreement made no "substantive changes" to Australia's pharmaceutical pricing regime, and that the U.S. extracted more significant changes to pharmaceutical IP rules through the negotiation of the NAFTA with Canada and Mexico.[64]

If AUSFTA foreshadows what the U.S. could negotiate with the U.K., the future is brighter for the NHS' pharmaceutical scheme than many opponents of a deal currently argue. The NHS maintains both a statutory mandate and a voluntary drug pricing scheme aimed at putting downward pressure on the program's pharmaceutical expenditures.[65] Rather than maintaining a centralized clearinghouse for drug prices like the PBS, Britain's system is instead a patchwork of price regulations depending on the drug's therapeutic use, its composition as a small-molecule or biologic medicine,[66] or its status as a generic.[67] The statutory scheme currently requires a fifteen percent markdown on branded pharmaceuticals launched before December of 2013.[68] As of 2014, only about six percent of NHS

62. *See* Tully, *supra* note 53, at 408.

63. *Id.*

64. Katherine Van Marent, *Bartering with a Nation's Health or Improving Access to Pharmaceuticals? The United States-Australia Free Trade Agreement*, 14 PAC. RIM L. & POL'Y J. 801 (2005).

65. LEO EWBANK, ET AL., THE KING'S FUND, THE RISING COST OF MEDICINES TO THE NHS: WHAT'S THE STORY? 20–22 (2018). Through a voluntary scheme, known as the Pharmaceutical Price Regulation Scheme (PPRS) the government negotiates with the British pharmaceutical industry every five to six years, *id.*

66. *See id.* at 34. The biologic versus small-molecule distinction is growing as a means of classifying drugs. Biologics derive their therapeutic use from lifeforms rather than chemical formations. Drug manufacturers cannot make "exact" copies of biologic medicines akin to a molecular generic drug, so the less expensive versions of biologics take the name "biosimilars." The NHS is still developing its policy on biosimilar prescriptions, and the policy as of 2018 requires a more affirmative process to transition a patient from biologic to biosimilar treatment, *id.*

67. *See id.* at 20–30.

68. *Id.* at 22–23.

pharmaceuticals were subject to the statutory scheme.[69] The U.K. government has promoted one overarching goal, however: encouraging doctors and pharmacists to prescribe generics in primary care cases.[70]

Here, the nature of the U.S. negotiating objectives for a U.K. deal relative to the AUSFTA talks are relevant. For the Australia deal, the George W. Bush administration relied on objectives set out in the Trade Act of 2002, a law which granted the administration the authority to negotiate a deal with Australia in accordance with the objectives.[71] The 2002 negotiating objectives did not directly reference pharmaceutical market access, but they did call for "ensuring that the provisions of any [agreement] governing intellectual property rights . . . reflect a standard of protection similar to that found in United States law," as well as for "fair, equitable, and nondiscriminatory market access opportunities for United States persons that rely upon intellectual property protection."[72] By contrast, the U.S.-U.K. objectives specifically reference pharmaceutical standards with respect to regulatory reimbursement and transparency.[73] Similarly, direct references to reimbursement schemes make no appearance in the 2002 Act's negotiating objectives.[74]

The U.S. pharmaceutical industry's continued complaints about its market access in Great Britain also underline the differences from the AUSFTA.[75] The Pharmaceutical Researchers and Manufacturers of America, an industry group commonly known by the abbreviation PhRMA, downplayed the linkage between increased healthcare spending and pharmaceutical costs in its annual comment submission for USTR's 2019 National Trade Estimate (NTE) report.[76] The

69. *Id.* at 22.

70. *Id.* at 33.

71. *See* Trade Act of 2002, Pub. L. No. 107-210, § 2102, 116 Stat. 933, 944.

72. *Id.* § 2102(b)(4).

73. *See* USTR NEGOTIATING OBJECTIVES, *supra* note 24, at 8.

74. *See* Trade Act of 2002.

75. *See, e.g.*, THE PHARM. RESEARCH & MFRS. OF AM., 2019 NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE) 196–99 (Oct. 2018) [hereinafter 2019 REPORT], http://phrma-docs.phrma.org/files/dmfile/PhRMA-2019-NTE-Comments.pdf; THE PHARM. RESEARCH & MFRS. OF AM., 2020 NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE) 225–28 (Oct. 2019) [hereinafter 2020 REPORT], http://phrma-docs.phrma.org/files/dmfile/PhRMA-2019-NTE-Comments.pdf.

76. *See* 2019 REPORT, *supra* note 75, at 198 ("PhRMA members recognize

group's 2020 submission reiterated this position, while also calling for the U.S. government to engage in a dialogue about the way the NHS' current administration restricts patient access to branded medicines.[77]

With the U.S. industry evidently clamoring for some sort of improved market access that requires changes to the NHS' administration and reimbursement mechanisms, it is less likely that AUSFTA's outcome will apply in a U.S.-U.K. negotiation. The PhRMA submissions note the likelihood of changed IP rules in the aftermath of Brexit and call for future U.S.-U.K. talks to "cement" the U.K.'s pharmaceutical IP rules or even seek more stringent standards.[78]

In such a case, it is plausible that a U.S.-U.K. deal could enshrine changes to the reimbursement or IP schemes through binding language in the deal's core text, rather than through a nonbinding side agreement such as AUSFTA. Indeed, the U.S. negotiating position has trended toward including more binding pharmaceutical provisions in agreements such as the proposed Trans-Pacific Partnership, which languished in Congress before Trump eventually shelved it.[79]

AUSFTA therefore represents a best-case scenario for NHS supporters who oppose interference through a trade deal. With its increased influence through the U.S. negotiating objectives, combined with the inherent leverage Brexit grants the U.S., the pharmaceutical industry can push the U.S. government to extract more binding concessions that could remake the NHS' pharmaceutical scheme and possibly lead to higher NHS spending on branded pharmaceuticals and a diminished emphasis on quick transitions to generic drugs.

B. South Korea-U.S. Trading Relationship

Several years after AUSFTA's conclusion, the Obama administration concluded negotiations with South Korea and

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the need to control drug spending in the NHS, but do not believe that spending on medicines is currently a driver of healthcare inflation in the UK.").

77. *See* 2020 REPORT, *supra* note 75, at 225–26.

78. *Id.* at 225.

79. *See* Alexander Stimac, Note, *The Trans-Pacific Partnership: The Death-Knell of Generic Pharmaceuticals*, 49 VAND. J. TRANSNAT'L L. 853 (2016). Stimac notes that the TPP sought binding language committing New Zealand's government to delay its timeline for purchasing generic pharmaceuticals for its PHARMAC national health system, *id.* at 873.

enacted the Korea-U.S. Free Trade Agreement, also known as KORUS.[80] The agreement built on AUSFTA's pharmaceutical provisions by altering the pharmaceutical reimbursement procedures in South Korea's national health care system, as well as other intellectual property and public health measures beyond what the U.S. and Australia addressed a few years prior.[81] The KORUS talks went beyond AUSFTA by adopting the U.S. industry's recommendation for an independent review process for the national health system's listing of qualifying drugs.[82] The agreement also binds countries to using the drug listing process to set prices at "competitive market-derived" values.[83] One observer has argued that the independent review process does not take into account the qualitative assessments that health systems make when attempting to determine whether to list a drug, and instead "may allow the pharmaceutical companies to disrupt the formulary one drug at a time" based on the assumption that all drugs are entitled to reimbursement.[84] PhRMA, in particular, could have sought these changes as a result of failed litigation against U.S. states that had set up similar preferred list regimes for their own Medicaid reimbursement programs, and that using the international trade negotiations was a means of gaining more leverage in other markets.[85] The U.S. negotiating position throughout KORUS was more aggressive regarding national health systems than it was during AUSFTA, and the KORUS talks served as a blueprint for the Trans-Pacific Partnership talks, which attempted to place stronger drug listing rules on countries like New Zealand and Australia.[86]

Beyond the perceived non-tariff barrier of preferred listing systems, KORUS also gave the U.S. pharmaceutical industry an opportunity to make changes to what it perceived as injustices and inefficiencies in other areas of the South Korean health

80. *See* Laura Chung, *AUSFTA, Korus FTA and Now TPP: Free Trade Agreements Are Now Reaching Further into Domestic Health Policies than Ever Before*, CURRENTS, Winter 2013, at 26, 27.

81. *Id.* at 26.

82. *Id.* at 27–28.

83. United States-Korea Free Trade Agreement, S. Kor.-U.S., art. 5.2, June 30, 2007, 46 I.L.M. 642; Chung, *supra* note 80, at 28.

84. Chung, *supra* note 80, at 28.

85. *Id.* States began to save money as a result of the preferred drug listing schemes, which courts upheld, and 40 states eventually adopted as of 2014, *id.* at 32.

86. *See id.* at 34.

system, such as intellectual property protections.[87] The South Korean market was especially important for the industry because of the country's aging population and corresponding increase in drug demand.[88] However, throughout KORUS' implementation period, the Korean government has also sought to relax IP restrictions for the purpose of allowing more access to generic medicines.[89] This has led to persistent industry complaints about Korean compliance with KORUS' provisions on procedural transparency.[90]

For these reasons, the pharmaceutical industry's increased pressure on the U.S. government and the topic of the more favorable IP restrictions that have resulted from KORUS could again arise in the U.K. negotiations. Despite regional differences, the U.K. and Korea have some similarities that could make the pharmaceutical industry push for the U.S. to take a line with the U.K. that resembles the KORUS talks.[91] If the industry views its access to the market of U.K. branded medicines consumers as crucially as it viewed its access to Korea's, the complaints about reimbursement and IP protections that appear in PhRMA's NTE submissions could extend into the negotiations and possibly arise as a complaint after an agreement's enactment and throughout the deal's implementation.

C. Investment, IP and Failed Obama-Era Trading Negotiations

Two international negotiations which occurred mostly simultaneously – the Trans-Pacific Partnership (TPP) talks with eleven Asia-Pacific countries and the Transatlantic Trade and Investment Partnership (TTIP) talks with the European Union – represented the peak so far of the industry's attempts to use

87. *See* Aerin Kim, Note, *Patent Protection Regulation and the Right to Health: Ripe for Discussion in Renegotiating KORUS-FTA*, 10 GEO. MASON J. INT'L COM. L. 53, 60 (2018).

88. *Id.*

89. *Id.*

90. *Id.* at 60–61.

91. *See* Miriam Quick & Valentina d'Efilippo, *South Korea's Population Paradox*, BBC (Oct. 14, 2019), https://www.bbc.com/worklife/article/20191010-south-koreas-population-paradox. South Korea's age demographics are slightly starker than the U.K.'s; the former has the world's lowest birthrate. However, similar issues of longer life expectancy combined with lower fertility rates resemble some of the demographic trends in the U.K., *id.*

trade agreements to get stronger protections for branded pharmaceuticals in other countries.

The TPP, whose members included Australia and New Zealand, would have increased "the degree of control that pharmaceutical companies have over how their products are sold" under systems like Australia's PBS and New Zealand's Pharmaceutical Management Agency (PHARMAC).[92] The TPP notably would have allowed major investors, including pharmaceutical companies, to seek an arbitral reward for the expropriation of patents or other investments in violation of the TPP's IP or medicines provisions.[93] The agreement also would have allowed firms to use ISDS to force member countries to permit patent evergreening, in effect allowing brand name protections to remain in place despite small changes to the molecular or biological structure of a drug, or even the drug's packaging.[94] Although stakeholder groups such as Doctors Without Borders noted that such a change would have a starker effect on developing countries than on nations with well-funded health systems like Australia and New Zealand, such provisions have been controversial both for potential direct effects on developed-country health systems and for downstream effects on access to generic medicines in developing countries.[95] TPP's effect on the PBS and PHARMAC were matters of significant controversy in Australia and New Zealand, but even more controversial was the ISDS mechanism's potential effect on the "plain packaging" laws that limit tobacco companies' legal right to sell branded cigarettes or other products.[96] The U.S., which is home to some of the world's largest tobacco firms,[97] conceded a

92. Stimac, *supra* note 79, at 874. The TPP would have required PBS and PHARMAC in particular to delay the marketing of generic medicines – an important concession to the branded pharmaceutical industry; see discussion *supra* Section I.B, for a more detailed explanation of evergreening.

93. *See* Stimac, *supra* note 79. The TPP's ISDS mechanism would have allowed this type of action, see discussion *supra* Section I.

94. *See* Stimac, *supra* note 79, at 872.

95. *See id.* An MSF policy expert described TPP at the time as one of the "most damaging" deals to date for poor people's access to medicines, *id.* at 874–75; *see also* Press Release, Médecins Sans Frontieres Access Campaign, MSF Urges TPP Countries Not to Abandon Public Health in Bid to Finalize Trade Deal (Feb. 20, 2014), https://msfaccess.org/msf-urges-tpp-countries-not-abandon-public-health-bid-finalize-trade-deal.

96. *See* Yu, *supra* note 52.

97. *See* Dominic Rushe, *Tobacco Companies Philip Morris and Altria in Talks to Reunite*, GUARDIAN (Aug. 27, 2019, 11:44 EDT), https://www.theguardian.com/business/2019/aug/27/tobacco-philip-morris-altria-merger-talks. Altria and Philip Morris International (PMI) are

carveout of the plain packaging laws from the ISDS mechanism.[98]

The British public's intense national pride for the NHS would likely make the service's protection just as high of a priority, if not a higher one, than PBS and PHARMAC were throughout TPP negotiations.[99] Skeptics who worry about the potential for ISDS to undermine NHS access to medicines, its budget, or its prioritization of generic medicines could look to the TPP's definition of "legitimate public health regulation" for hope.[100] That definition, which never entered into force, limited regulatory actions that fall within ISDS' ambit if they relate to "the regulation, pricing and supply of, and reimbursement for, pharmaceuticals (including biological products)" and other products.[101] TPP negotiators included the limited definition to further outline how ISDS would cover regulatory "takings" – a concept which the U.S. has successfully exported to some trade partners through ISDS.[102] But even when an agreement's text appears to include carveouts for matters of public health or other sensitive issues, the ISDS tribunals themselves "often interpret provisions in such a way as to limit their application."[103] Because agreements like TPP (as well as the boilerplate language for U.S. bilateral investment treaties known as the Model BIT text) provide no further assistance to adjudicators regarding how to interpret such definitions, the risk of an investor-friendly panel ordering a reward for a potential regulatory taking could be high under a similar U.S.-U.K. arrangement.[104] This uncertainty relating to environmental and social protections prompted Australia to withhold its approval of TPP's investment chapter.[105]

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respectively worth $88 billion and $121 billion; they are considering a merger which would make them an even larger force both within the global tobacco industry and within the United States, *id.*

98. Thomas J. Bollyky, *TPP Tobacco Exception Proves the New Rule in Trade*, COUNCIL ON FOREIGN REL. (Feb. 4, 2016, 11:26 AM), https://www.cfr.org/expert-brief/tpp-tobacco-exception-proves-new-rule-trade.

99. *See* discussion *supra* Introduction.

100. *See* Trans-Pacific Partnership, annex 9-B, Feb. 4, 2016, https://ustr.gov/sites/default/files/TPP-Final-Text-Investment.pdf.

101. *See id.* at n.37. The other covered measures included those related to "diagnostics, vaccines, medical devices, gene therapies and technologies, health-related aids and appliances and blood and blood-related products," *id.*

102. *See* Giest, *supra* note 50, at 344.

103. *Id.* at 343.

104. *Id.* at 345.

105. *Id.*

The TTIP negotiations with the EU, which were undertaken while the U.K. still belonged to the Union, could further inform NHS proponents when viewed alongside the TPP's final text. The hard U.S. line on a number of matters important to European negotiators, including those which were priorities for the U.K., make it less likely that the U.S. will grant concessions on sensitive British issues in the bilateral context.[106] Right-wing U.K. politicians even appeared to recognize this during the early days of negotiations. The U.K. Independence Party initially supported the EU-U.S. talks in part because of their potential to import U.S. healthcare standards, and in turn open the NHS to more private sector activity.[107] The new Tory government, while not aligned directly with UKIP, adopted UKIP positions like Brexit in exchange for more diplomatic ties with the United States.[108] This fact would make NHS privatization through a trade agreement more foreseeable.[109]

D. Potential Resolutions and Solutions

This section will evaluate potential solutions that could ameliorate concerns on both sides of the NHS issue as they relate to both IP protection and ISDS. The first potential compromise is a stronger carveout of NHS-related measures from the ISDS mechanism, while language preserving the status quo could also assuage both investors and civil society.

One scholar has described excluding IP rights from the ISDS ambit as a simple means of protecting public health decisions from challenges.[110] This would take the form of language excluding situations such as the *Eli Lilly* case, wherein ISDS

106. ALASDAIR R. YOUNG, THE NEW POLITICS OF TRADE: LESSONS FROM TTIP 135–36 (Erik Jones ed., 2017).

107. *See* Julia Rone, *Contested International Agreements, Contested National Politics: How the Radical Left and the Radical Right Opposed TTIP in Four European Countries*, 6 LONDON REV. INT'L L. 233, 240–42 (2018).

108. Owen Jones, *Tories Courted the Ukipper: Now They'll Be Consumed by Them*, GUARDIAN (Aug. 30, 2018, 11:36 EDT), https://www.theguardian.com/commentisfree/2018/aug/30/tories-ukip-britain-entryism ("While dozens of Tory councillors defected to Ukip under David Cameron's leadership, one report suggests at least 10% of Ukip councillors have gone the other way since 2015.").

109. Rob Crilly, *Brexit Leader Nigel Farage Will Return to US to Campaign for Trump in 2020*, WASH. EXAMINER (Dec. 10, 2019), https://www.washingtonexaminer.com/news/brexit-leader-nigel-farage-will-return-to-us-to-campaign-for-trump-in-2020.

110. *See* Ho, *supra* note 39, at 297–98.

would be available for investors wishing to challenge a domestic policy change.[111] At the same time, it would further clarify that the types of "intangible investments" often covered under ISDS do not include certain intellectual property protections, including common law protections.[112] Additionally, more strictly worded language clarifying the meaning of a term such as "public health" could also give the NHS or British courts more leeway to decide on IP issues without raising an *Eli Lilly*-type of problem.[113] Because the main problem with public health carveouts has been their open-endedness, more clarity about what NHS actions would be exempt would make the program's more sensitive areas immune from private interference and preserve the industry's interest in greater transparency outlined in the U.S. negotiating objectives.[114] A U.S.-U.K. carveout could go even further by not just protecting Britain's right to regulate specific health issues such as tobacco, but also expressly exempting certain sensitive NHS functions from ISDS adjudication. This would allow for highly specific exemptions on certain NHS processes or programs, while also allowing the U.S. industry to access ISDS for other IP or regulatory developments it considers unfair. Doing so could be very difficult for U.K. negotiators, however, because of the tobacco industry's declining social influence relative to the pharmaceutical sector.[115]

Negotiating the NHS' ability to set price caps would represent a more drastic, possibly deal-breaking attempt at compromise from PhRMA's perspective. The flexibility for a government with a national health service to set down such caps or issue compulsory licenses is crucial in the event of a public health crisis, and goes to the very core of a government-run

111. *Id.* at 298.

112. *Id.* at 298–99.

113. *See id.* at 296.

114. *See supra* Section I.

115. *See Tobacco and Smoking*, GALLUP, https://news.gallup.com/poll/1717/tobacco-smoking.aspx (last visited Apr. 17, 2020) (demonstrating how tobacco consumption is waning significantly in the United States – just 15% of respondents surveyed in a 2019 Gallup poll said they had smoked in the last week, compared to as many as 45% of respondents in the 1950s and 27% in the 1990s. *See also* Justin McCarthy, *Big Pharma Sinks to the Bottom of U.S. Industry Rankings*, GALLUP (Sept. 3, 2019), https://news.gallup.com/poll/266060/big-pharma-sinks-bottom-industry-rankings.aspx. Large pharmaceutical companies, despite their political influence, are still not that popular with the public. In a separate 2019 survey, Gallup found that the sector had a net -31% favorability rate – worse than the airline industry, the oil and gas industry, and the legal services industry, *id.*

health system's mission.[116] Although the WTO itself has noted that compulsory licenses are not exclusively used during health crises, this is perhaps their most important function.[117] The current TRIPS arrangement also preserves states' ability to determine their own grounds for allowing compulsory licenses, as well as what constitutes a national emergency.[118] Additionally, enshrining price caps or other emergency measures in the text of an agreement would preserve the U.S. industry's goal of improved and nondiscriminatory transparency.[119]

Finally, maintaining the status quo by making a U.S.-U.K. deal integrate more with the TRIPS arrangement could also assuage both sides of the NHS debate. One suggestion calls for agreements which specify that an ISDS panel may only adjudicate an IP dispute pursuant to the text of the agreement itself, rather than pursuant to existing international IP regimes such as TRIPS.[120] In this manner, U.S. industry would get their ISDS mechanism while also providing NHS public health measures protection from an industry-favorable arbitral panel. This would have the added benefit of avoiding conflicting decisions between an ISDS panel and a WTO dispute settlement panel on the merits of a TRIPS issue.[121] However, the WTO dispute settlement system has faced a high volume of persistent complaints that has created a significant backlog of cases.[122] Because of this ongoing crisis in Geneva, the U.S. and the U.K.

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116. *See* Kim, *supra* note 87, at 69–72. A compulsory license is a government-issued permit for a non-patentholder to produce a patented pharmaceutical, *id.* at 69. In times of a public health crisis, this lowers the cost of emergency medicines and makes them more available to authorities and affected patients, *id.* at 71–72. TRIPS permits such an arrangement, but they are frequently controversial in independent "TRIPS-Plus" agreements the U.S. negotiates, *id.* at 69.

117. *TRIPS and Health, Frequently Asked Questions: Compulsory Licensing of Pharmaceuticals and TRIPS*, WTO, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Jan. 24, 2020).

118. *Id.*

119. *See supra* Section I.

120. Ho, *supra* note 39, at 298–99.

121. *Id.* at 299 (asserting that this approach would "prevent commercial arbitrators from usurping the process for determining TRIPS compliance, which could lead to inconsistent judgments").

122. *See generally* TETYANA PAYOSOVA ET AL., PETERSON INST. FOR INT'L ECON., POLICY BRIEF 18-5, THE DISPUTE SETTLEMENT CRISIS IN THE WORLD TRADE ORGANIZATION: CAUSES AND CURES (2018), https://www.piie.com/system/files/documents/pb18-5.pdf.

may not be willing to assuage the pharmaceutical industry by settling more IP disagreements through the WTO process, as opposed to through the comparatively more efficient bilateral dispute settlement mechanisms.

III. Conclusion

The political situations in both the U.S. and the U.K. are highly flexible given Britain's transition away from the EU,[123]the fallout from the 2020 U.S. presidential election, as well as the consequences of the COVID-19 crisis which will likely remain relevant for years. The Conservative victory in the December 2019 parliamentary general election ensures that Boris Johnson will lead the U.K.'s side for at least several years, barring any snap elections.[124] Following Trump's defeat in the 2020 election, the pharmaceutical industry could continue to exert significant influence over a bilateral trade agreement.[125] Notably, President Joe Biden was a forceful advocate for the

123. *See* Stephen Castle, *U.K. Takes a Major Step Toward Brexit*, N.Y. TIMES (Jan. 22, 2020), https://www.nytimes.com/2020/01/22/world/europe/brexit-withdrawal-bill.html (describing Parliament's agreement to move forward with a formal withdrawal from the EU on Jan. 31, 2020).

124. *Cf.* Morgan Chalfant, *Trump, Boris Johnson Discuss 'Ambitious' Free Trade Agreement*, HILL (Dec. 16, 2019, 1:32 PM), https://thehill.com/homenews/administration/474751-trump-boris-johnson-discuss-ambitious-free-trade-agreement-uk-spox (noting Johnson's victory in the general election).

125. As this Note went to press, Biden had just been projected as the winner of the 2020 U.S. Presidential election, and specific details of his planned trade policy or who he would nominate for key trade-related positions such as USTR remained unclear. *See* William Booth & Karla Adam, *Boris Johnson's Brexit Has a Joe Biden Problem*, WASH. POST (Nov. 12, 2020, 7:08 PM), https://www.washingtonpost.com/world/europe/boris-johnson-biden-brexit/2020/11/12/2d0e889a-2396-11eb-9c4a-0dc6242c4814_story.html. In a post-election telephone call with Johnson, Biden raised the delicate question of balancing Britain's departure from the EU with the preservation of the free movement of people between Northern Ireland and the Republic of Ireland permitted under the 1998 Good Friday Agreement. As a candidate, Biden said that a trade agreement must be "contingent upon respect for the agreement and preventing the return of a hard border" between Northern Ireland and the Republic, which is an EU member state, *id*. *See also* Andrew Woodcock, *Boris Johnson Admits Trade Deal with US Under Biden Will Not Be a 'Pushover'*, INDEPENDENT (Nov. 10, 2020, 4:56 PM), https://www.independent.co.uk/news/uk/politics/boris-johnson-biden-uk-us-trade-deal-b1695183.html. Publicly, Johnson expressed cautious optimism that talks would still be possible under the Biden administration, and said "there's a good chance we'll do something," despite taking a continued hard line on the Ireland matter, *id*.

TPP, which the Obama administration negotiated.[126] Biden has backtracked on this support, singling out stronger environmental and labor provisions as a necessary improvement to the deal while not addressing pharmaceutical provisions.[127] Other front-runners for the Democratic nomination who retain influence within the party, such as Senators Bernie Sanders and Elizabeth Warren, were highly critical of the TPP.[128] The pair are skeptical of the current U.S. negotiating position on trade, which they have criticized, in part, as an example of regulatory capture.[129] Following Biden's victory, it appears Prime Minister Johnson's interlocutor will at least take interest in hearing and responding to the pharmaceutical industry's concerns regarding the NHS.[130] This makes the efforts of the NHS status quo's supporters particularly important.

The best outcome for those stakeholders is one resembling AUSFTA. Nonbinding language would allow for U.S.

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126. See Michael Crittenden & William Mauldin, *Biden Defends Merits of Trans-Pacific Partnership Trade Talks*, WALL ST. J. (Feb. 14, 2014, 7:11 PM), https://www.wsj.com/articles/biden-defends-merits-of-transpacific-partnership-trade-talks-1392422959, for a discussion of Biden's support for the TPP as vice president.

127. Nathaniel Weixel, *Biden: I Would 'Renegotiate' Pacific Trade Deal*, HILL (July 31, 2019, 10:22 PM), https://thehill.com/policy/international/455668-biden-i-would-renegotiate-pacific-trade-deal; *see also* Mark Landler, *U.K. Officials' New Trump Dilemma: What if He Loses?*, N.Y. TIMES (July 31, 2020), https://www.nytimes.com/2020/07/31/world/europe/britain-biden-presidency-johnson.html ("Were Mr. Biden to win, expert said, he would face a Democratic Party deeply skeptical of a deal, at a time when free trade is in retreat worldwide.").

128. *Bernie Sanders: 'Elizabeth Warren and I Will Help Lead the Effort" to Stop TPP*, REALCLEARPOLITICS (Oct. 7, 2015), https://www.realclearpolitics.com/video/2015/10/07/bernie_sanders_elizabeth_warren_and_i_will_help_lead_the_effort_to_stop_tpp.html.

129. Hilary Matfess, *The Progressive Case for Free Trade*, VOX (Aug. 1, 2019, 4:00 PM), https://www.vox.com/policy-and-politics/2019/8/1/20750506/elizabeth-warren-trade-policy-bernie-sanders-tpp-2020-democrats-progressives (describing both Sanders's and Warren's view that multinational firms have too much influence over the trade policymaking process compared to labor or other civil society interests).

130. See Simon Lester, *What Would Trade Policy Look Like Under a President Joe Biden?*, CATO: AT LIBERTY (March 11, 2020, 10:51 AM), https://www.cato.org/blog/what-would-trade-policy-look-under-president-joe-biden. Biden could use standalone negotiations with the U.K. as a means of setting out a template for future, TTIP-style discussions with the European Union. Biden's positions on pharmaceutical IP and drug pricing also differ significantly from Sanders's, *id*. *See also* Sarah Karlin-Smith & Sarah Owermohle, *Biden and Sanders Far Apart on Drug Pricing*, POLITICO (March 10, 2020, 12:00 PM), https://www.politico.com/newsletters/prescription-pulse/2020/03/10/biden-and-sanders-far-apart-on-drug-pricing-488528.

pharmaceutical companies to raise their concerns in the context of compliance with a bilateral deal. Such language would also preserve the future U.K. government's ability to take measures it believes are necessary to protect the NHS' budget, or to protect access to medicines, without worrying about the potential obligations of the bilateral agreement.

A full carveout of measures related to medicines from ISDS represents an even more hardline, but also more certain, outcome for those who worry about undermining the NHS through a free trade deal. While this outcome is unrealistic because of the general industry attachment to the ISDS mechanism, it would essentially preserve the status quo by forcing IP disputes related to the NHS into the state-to-state WTO dispute settlement process.[131] Moreover, despite some of the uncertainty surrounding how a left-wing U.S. administration with the same priorities as Senator Sanders or Senator Warren would negotiate a trade agreement, such a carveout could also be a means of shutting out the U.S. pharmaceutical industry in favor of a deal that harmonizes standards or tariffs on other issues.

The worst outcome for the NHS status quo would be binding language either resembling the KORUS pharmaceutical provisions or something going beyond the TPP's application to schemes such as the Australian PBS. Such language would give the pharmaceutical industry one of two options. In the KORUS situation, it would allow the industry to raise persistent complaints about any U.K. government's compliance akin to PhRMA's current complaints about South Korea's KORUS compliance. Also risky for current NHS stakeholders are full, unfettered inclusion of ISDS measures, in addition to specific binding language on sensitive IP issues such as compulsory licensing, drug pricing transparency, or data exclusivity for biologic medicines.

Negotiating any trade agreement requires addressing issues, tariff lines and industries that are sensitive to all parties. The NHS, however, is unique because of its special role in British society as well as current concern over its budgetary sustainability. Although Prime Minister Johnson's new government appears to have a mandate to strengthen economic ties with the United States through a trade agreement, the sustainability of the NHS was also a major domestic issue

131. *See supra* Section II.D.

throughout the 2019' general election campaign and will only grow more relevant amid the ongoing COVID pandemic.[132] Because of concerns that emerged during the campaign that the U.S. negotiators viewed NHS drug pricing as a "key consideration" during bilateral talks, members of British civil society have grown worried that a trade deal would strengthen the country's strategic and economic ties with the U.S. at the expense of a continued downward spiral for drug availability and the NHS' budget.[133] To avoid such an outcome, the preservation of nonbinding language, or language maintaining the status quo, must be among the U.K. government's top priorities in bilateral agreement negotiations.

APPENDIX I: TABLE OF ACRONYMS

AUSFTA	Australia-U.S. Free Trade Agreement
ISDS	Investor-State Dispute Settlement
KORUS	Korea-U.S. Free Trade Agreement
NTE	National Trade Estimate (Annual U.S. Government report on trade and trade barriers)
NHS	National Health Service (United Kingdom)
PBS	Pharmaceutical Benefits Scheme (Australia)
PhRMA	Pharmaceutical Researchers and Manufacturers of America
PHARMAC	Pharmaceutical Management Agency (New Zealand)
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TPP	Trans-Pacific Partnership
TTIP	Transatlantic Trade and Investment Partnership

132. *See* Benjamin Mueller, *U.K. Health Service Poses a Late Election Issue for Boris Johnson*, N.Y. TIMES (Dec. 10, 2019), https://www.nytimes.com/2019/12/10/world/europe/nhs-election-boris-johnson.html.

133. *Id.*

USTR	Office of the United States Trade Representative
VPAS	Voluntary Pricing and Access Scheme (NHS)