IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

JOHN KELLEY, *et al.*, Plaintiffs, v. XAVIER BECERRA, *et al.*, Defendants.	Civil Action No. 4:20-cv-00283-O

DEFENDANTS' SUPPLEMENTAL FILING REGARDING CROSS-MOTIONS FOR SUMMARY JUDGMENT

At the July 26, 2022 hearing on the parties' cross-motions for summary judgment, the Court asked the undersigned whether the Secretary of Health and Human Services (the "Secretary") can "override a nonrecommendation" of or, in other words, impose a coverage requirement under 42 U.S.C. § 300gg-13 absent a prior recommendation of, any of the three entities referenced in subsection (a) of that statute.[1] The undersigned agreed to respond in writing after confirming with Defendant agencies. Defendants hereby respond as follows:

1. **HRSA:** Yes, the Secretary is empowered to direct HRSA to include particular care and screenings in the guidelines they support under 42 U.S.C. § 300gg-13(a)(3) and (a)(4), pursuant to his authority over the Public Health Service of the United States, see, for example, 42 U.S.C. § 202 and Reorganization Plan No. 3 of 1966, 31 Fed. Reg. 8855 (June

[1] The three entities are the United States Preventive Services Task Force ("PSTF"), the Advisory Committee on Immunization Practices ("ACIP"), and the Health Resources and Services Administration ("HRSA").

25, 1966), 5 U.S.C. app. 1. See also Defs.' Br. in Supp. of Resp. ("Cross-Mot.") at 5-6, 29, ECF No. 64; Defs.' Reply at 23-25, ECF No. 83.

2. **ACIP:** Yes, the Secretary is empowered to direct ACIP's recommendation of specific vaccines such that those recommendations directed by the Secretary take "effect" pursuant to 42 U.S.C. § 300gg-13(a)(2). Moreover, unlike with respect to the preventive services considered by the PSTF and HRSA, federal law does not permit ACIP to decline to issue a recommendation regarding any licensed vaccine or indication for a vaccine. ACIP is required by law to consider the use of any vaccine at ACIP's next scheduled meeting after "the licensure of [that] vaccine or any new indication for [that] vaccine [if the vaccine was previously licensed for a different indication]," and at a minimum provide a report on the status of its review if there is not sufficient time to make a recommendation between licensure and that meeting. 21st Century Cures Act, Pub. L. No. 114-255, § 3091, 130 Stat. 1033, 1149-50 (Dec. 13, 2016) (attached as Exhibit A hereto). Accordingly, there should be no licensed vaccines or vaccine uses as to which ACIP declines to issue a recommendation. However, if for some reason ACIP were to decline to issue a recommendation for a particular licensed vaccine or use of a vaccine, ACIP's Designated Federal Officer, a federal employee selected by the CDC, could add consideration of that vaccine to the agency's next meeting agenda. *See* App'x to Defs' Br. ("App'x"), ECF No. 65 at APP 150.

At the conclusion of the meeting, the CDC Director (who acts under the Secretary's supervision and direction pursuant to his authority over the Public Health Service) is empowered to adopt or otherwise amend any recommendation or "nonrecommendation" made at ACIP's meeting. (Defendants provided an example of the CDC Director making

a broader recommendation than ACIP's initial recommendation at footnote 26 on page 38 of their cross-motion.) It is this final "recommendation" adopted by the CDC Director that takes "effect" for purposes of 42 U.S.C. § 300gg-13(a)(2)'s coverage requirement. *See* App'x at APP 149 ("[U]nder provisions of the Affordable Care Act . . . immunization recommendations of [ACIP] that have been adopted by the [CDC Director] must be covered by applicable health plans."); *see also* 45 C.F.R. § 147.130(a)(1)(ii). The Secretary or CDC Director could also exercise their removal authority over recalcitrant ACIP members. *See* Cross-Mot. at 5 (noting that ACIP "[m]embers are selected by the Secretary . . . and . . . are removable at will").

3. **PSTF:** The Secretary may not, consistent with 42 U.S.C. § 299b-4(a)(6), direct that the PSTF give a specific preventive service an "A" or "B" rating, such that it would be covered pursuant to 42 U.S.C. § 300gg-13(a)(1). *See* 42 U.S.C. § 299b-4(a)(6) ("All members of the [PSTF], and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure."). The Secretary could, however, remove members of the PSTF who were unwilling to provide an "A" or "B" rating to a particular service pursuant to his authority over the Public Health Service, in general, and the Agency for Healthcare Research and Quality ("AHRQ"), in particular. *See* 42 U.S.C. § 299(a) ("There is established within the Public Health Service an agency to be known as the Agency for Healthcare Research and Quality, which shall be headed by a director appointed by the Secretary. The Secretary shall carry out this subchapter acting through the Director."); 42 U.S.C. § 299b-4(a)(1) ("The [AHRQ] Director shall convene an independent Preventive Services Task Force . . . to be composed of individuals with appropriate expertise."); *see also* App'x at APP 067, § 1.5.1. As

Defendants argued in their briefing, to the extent that the Court concludes that this restriction creates a problem under the Appointments Clause or Vesting Clause, the appropriate remedy is to hold 42 U.S.C. § 299b-4(a)(6)'s restriction on the Secretary's control over the PSTF unconstitutional in the context of the Preventive Services Provision, but otherwise uphold the Preventive Services Provision and the PSTF's recommendations. *See* Cross-Mot. at 47; Defs.' Reply at 27.

Respectfully submitted,

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Certificate of Service

On August 2, 2022, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all parties who have appeared in the case electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Christopher M. Lynch
Christopher M. Lynch

Exhibit A

CONGRESS.GOV

H.R.34 - 21st Century Cures Act

114th Congress (2015-2016)

Sponsor: Rep. Bonamici, Suzanne [D-OR-1] (Introduced 01/06/2015)
Committees: House - Science, Space, and Technology | Senate - Commerce, Science, and Transportation
Committee Reports: S. Rept. 114-146
Committee Prints: H.Prt. 114-67
Latest Action: 12/13/2016 Became Public Law No: 114-255. (All Actions)
Roll Call Votes: There have been 3 roll call votes
Tracker: Introduced > Passed House > Passed Senate > Resolving Differences > To President > **Became Law**

Summary(4) **Text(8)** Actions(63) Titles(14) Amendments(15) Cosponsors(7) Committees(2) Related Bills(48)

There are 8 versions: Public Law (12/13/2016)

Text available as: TXT | PDF (966KB)

Shown Here:
Public Law No: 114-255 (12/13/2016)

[114th Congress Public Law 255]
[From the U.S. Government Publishing Office]

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Public Law 114-255
114th Congress

An Act

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes. <>

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, <>

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) Short Title.--This Act may be cited as the ``21st Century Cures Act''.

(b) Table of Contents.--The table of contents for this Act is as follows:

(3) in subsection (e)(3)(B), by striking ``section 503(b)'' and inserting ``subsection (b) or (f) of section 503 or under section 504'';

(4) in subsection (f)(2)--

(A) by inserting ``, or an animal to which,'' after ``to a patient to whom''; and

(B) by inserting ``or by the veterinarian caring for such animal, as applicable'' after ``attending physician'';

(5) in subsection (g)(1), by inserting ``conditional approval under section 571,'' after ``approval,'';

(6) in subsection (h)(1), by striking ``or section 520(g)''and inserting ``512(j), or 520(g)''; and

(7) in subsection (k), by striking ``section 520(g),''and inserting ``512(j), or 520(g)''.

(b) New Animal Drugs.--Section 512(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(a)(1)) is amended--

(1) in subparagraph (B), by striking ``or'' at the end;

(2) in subparagraph (C), by striking the period and inserting ``; or''; and

(3) by inserting after subparagraph (C) the following:

``(D) there is in effect an authorization pursuant to section 564 with respect to such use or intended use of such drug, and such drug, its labeling, and such use conform to any conditions of such authorization.''.

(c) Emergency Use of Medical Products.--Section 564A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3a) is amended--

(1) in subsection (a)(1)(A), by inserting ``, conditionally approved under section 571,'' after ``chapter''; and

(2) in subsection (d), by striking ``sections 503(b) and 520(e)'' and inserting ``subsections (b) and (f) of section 503, section 504, and section 520(e)''.

(d) Products Held for Emergency Use.--Section 564B(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3b(2)) is amended--

(1) in subparagraph (A)--

(A) by inserting ``or conditionally approved under section 571 of this Act'' after ``Public Health Service Act''; and

(B) by striking ``or 515'' and inserting ``512, or 515''; and

(2) in subparagraph (B), by striking ``or 520'' and inserting ``512, or 520''.

Subtitle I--Vaccine Access, Certainty, and Innovation

SEC. 3091. <> PREDICTABLE REVIEW TIMELINES OF VACCINES BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.

(a) Consideration of New Vaccines.--Upon the licensure of any vaccine or any new indication for a vaccine, the Advisory

Committee on Immunization Practices (in this section referred to as the ``Advisory Committee'') shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting.

(b) Additional Information.--If the Advisory Committee does not make a recommendation with respect to the use of a vaccine at the Advisory Committee's first regularly scheduled meeting after the licensure of the vaccine or any new indication for the vaccine, the Advisory Committee

shall provide an update on the status of such committee's review.

(c) Consideration for Breakthrough Therapies and for Potential Use During Public Health Emergency.--The Advisory Committee shall make recommendations with respect to the use of certain vaccines in a timely manner, as appropriate, including vaccines that--

(1) are designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) and licensed under section 351 of the Public Health Service Act (42 U.S.C. 262); or

(2) could be used in a public health emergency.

(d) Definition.--In this section, the terms ``Advisory Committee on Immunization Practices'' and ``Advisory Committee'' mean the Advisory Committee on Immunization Practices established by the Secretary pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.''.

SEC. 3092. REVIEW OF PROCESSES AND CONSISTENCY OF ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES RECOMMENDATIONS.

(a) Review.--The Director of the Centers for Disease Control and Prevention shall conduct a review of the processes used by the Advisory Committee on Immunization Practices in formulating and issuing recommendations pertaining to vaccines, including with respect to consistency.

(b) Considerations.--The review under subsection (a) shall include an assessment of--

(1) the criteria used to evaluate new and existing vaccines, including the identification of any areas for which flexibility in evaluating such criteria is necessary and the reason for such flexibility;

(2) the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to the review and analysis of scientific and economic data, including the scientific basis for such approach; and

(3) the extent to which the processes used by the work groups of the Advisory Committee on Immunization Practices are consistent among such groups, including the identification of reasons for any variation.

(c) Stakeholders.--In carrying out the review under subsection (a), the Director of the Centers for Disease Control and Prevention shall solicit input from vaccine stakeholders.

(d) Report.--Not later than 18 months after the date of enactment of this Act, the Director of the Centers for Disease Control and Prevention shall submit to the appropriate committees of the Congress, and make publicly available, a report on the results of the review under subsection (a), including any recommendations

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on improving the consistency of the processes described in such subsection.

(e) Definition.--In this section, the term ``Advisory Committee on Immunization Practices'' means the Advisory Committee on Immunization Practices established by the Secretary of Health and Human Services pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.

SEC. 3093. <> ENCOURAGING VACCINE INNOVATION.

(a) Vaccine Meetings.--The Director of the Centers for Disease