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DRUG SHORTAGES: FDASIA AND INCENTIVES FOR COMPLIANCE THROUGH THE TAX CODE

Robert Alinsky*

I. INTRODUCTION

The Food and Drug Administration Safety and Innovation Act (FDASIA) became law in July 2012 and authorizes the Federal Drug Administration (FDA) to take more aggressive action in combating drug shortages in the U.S.¹ FDASIA provides the FDA with new tools to better prepare for impending shortages such as more strict reporting requirements for pharmaceutical companies engaged in the manufacture of certain covered drugs.² However, while an alert system is important, the new law does not directly address the underlying issue of how to prevent drug shortages by ensuring an adequate supply.³ As many public, private, and governmental organizations stress, drug shortages is a pressing issue affecting many people who rely on critical medications. This issue needs immediate aggressive legislative attention.⁴ The FDA is seeking solutions to this problem and is open to working with pharmaceutical companies to increase production of certain drugs.⁵ In addition to the existing early warning system, one possible solution would be to use the tax code to create positive incentives for drug manufacturers to prevent and relieve drug shortages. This article argues to broaden the scope of the Increasing Research Activities Credit to cover pharmaceutical company expenses targeted at drug shortages, and that the calculation of the credit could be based on the formula employed in the Renewable Energy Production Credit.⁶

II. BACKGROUND

Under FDASIA's broad-stroke policy objectives aimed at reducing drug shortages, the FDA is required to establish a Drug Shortages Task Force (Task Force) whose responsibility is to develop and

implement a drug shortages plan.⁷ The Task Force has since opened its plan development to public comments and has articulated a number of areas in which they seek specific suggestions.⁸ One such item the Task Force seeks comments on are "incentives that FDA can provide to encourage manufacturers to establish and maintain high-quality manufacturing practices, to develop redundancy in manufacturing operations, to expand capacity, and/or to create other conditions to prevent or mitigate shortages."⁹ The tax system can be utilized for such incentive behavior.¹⁰ One available avenue is to employ the current Increased Research Activities credit and incorporate into that credit the formula used in the highly successful Energy Production Credit for renewable fuels.

A. FDASIA

Congress updated The Federal Food, Drug & Cosmetic Act (FD&C Act) through FDASIA by amending certain provisions which now require pharmaceutical companies to notify the FDA of impending shortages and to keep records of drug levels.¹¹ The FDA was further instructed to facilitate better inter- and intra-agency communication about drug shortages and use a Task Force to form a strategic plan to thwart shortages.¹² The Task Force seeks solutions to attack the underlying problems of drug shortages including encouraging increased manufacturing, exploring better metrics for monitoring drug levels, and incentivizing pharmaceutical companies to "establish and maintain high-quality manufacturing practices, to develop redundancy in manufacturing operations, to expand capacity, and/or to create other conditions to prevent or mitigate shortages."¹³

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B. Increased Research Credit

Under 26 U.S.C. § 41, the tax code provides corporations with a non-refundable incremental tax credit for increased qualified research expenses and activities.¹⁴ The credit is limited to certain activities outlined in a four-part test, requiring: expenses that qualify as research under 26 USC § 174; technological in nature; involves a business component; and involves a process of experimentation related to a qualified purpose.¹⁵ To satisfy the business component element, expenses must be related to research regarding products, process, formulas, or software, which are to be held for sale, lease, or used in the organization's trade or business.¹⁶ The purposes for which the credit is to be applied are limited to those related to a new or improved function, performance, or reliability and quality.¹⁷ Permitted purposes do not include, among other things, research after commercial production has begun, adapting a business component to a particular customer's needs, or duplication of an existing business component.¹⁸ Seemingly narrow, the code could be broadened by interpreting what the permitted purposes apply to and should be read to mean.¹⁹

C. Renewable Energy Production Credit

Intended to incentivize production of alternative energy sources to fossil fuels, the Renewable Energy Production Credit permits a tax credit to production facilities that produce electricity from renewable sources.²⁰ The credit is calculated by a simple mathematical formula based on the amount of electricity actually produced by the qualified facility.²¹ This tax credit has successfully incentivized the use of alternative fuels to produce electricity, and the production-dependent formula used to calculate the credit is directly related to increased production of electricity by renewable energy.²²

III. ANALYSIS

The Task Force's recent comment period sought suggestions from the public to help relieve drug shortages. Notably, the Task Force announced that it is looking for ways to work with other federal government agencies to accomplish its mission.²³

The Treasury Department can provide a resource to the FDA in this regard by promulgating regulations or pressuring congress for a bill that would incentivize pharmaceutical companies to maintain sufficient quantities, more effectively monitor drug levels, and/or resume manufacturing of drugs that the FDA determines are in shortage.²⁴ Sections 41 and 45 of the tax code could be used together to promote synergy between pharmaceutical companies and the FDA to improve manufacturing mechanisms, processes, and supply monitoring systems of the critical drugs needed by many Americans.

A. Reinterpret § 41 to Accommodate FDASIA Objectives

Faster and more efficient than asking Congress to pass a bill granting new authority to Treasury or the FDA, the Task Force should work with Treasury to draft new interpretive, legislative, or procedural regulations to expand the scope of the Increasing Research Credit to include stop-gap drug shortage efforts by drug companies. The new regulation should interpret the qualified research language in § 41 to include such measures that allow a company to easily and quickly produce more of an essential drug.²⁵ Moreover, the regulation's authority is linked to the policy objectives of Congress, which support incentivizing the pharmaceutical industry through tax credits.²⁶ The statute is intended to incentivize research activities, and such activities will benefit society if they include pharmaceutical efforts to increase production of drugs that are facing a critical level of supply as prescribed by the FDA.²⁷

Although the credit is limited to certain purposes, the current language of the credit encompasses the type of costs associated with activities outlined in FDASIA objectives.²⁸ Funds spent towards meeting FDASIA's goal of research and implementation of new processes to prevent shortages and maintain adequate drug supplies meet the requirements of § 41: expenditures made in discovering new technological information relating to a new or improved function, performance, or reliability or quality of a business component.²⁹ The language of the statute is broad enough to encompass the intent of FDASIA by allowing a credit for pharmaceutical

companies who invest funds in better tools and new methods in order to improve their ability to prevent shortages and continue or restart manufacturing when the FDA alerts that supplies are low.³⁰ However, Treasury should work with the Task Force to develop language that reinterprets the scope of the credit to cover broader costs associated with developing systems to better monitor drug stockpiles for the enumerated drugs listed by FDA. Additionally, a Treasury regulation could better explain the “reliability” function of permitted purposes of § 41(d)(3)(iii) to account for expenses used to increase reliability of drug manufacturing practices. This would encourage production of better quality products, which would increase overall drug stock and reduce costs associated with defective drug units.³¹ A regulation could also interpret § 41 and associated treasury regulations to limit the disallowed purposes of products already manufactured or duplication of business competent by outright excluding such research activities pertaining to drug shortages.³²

B. Incorporate the Renewable Energy Production Credit Formula

To further achieve the goals of the FDASIA Task Force, a treasury regulation should further interpret and adjust procedurally how the credit will be calculated based on the methodology used in calculating the Energy Production Credit.³³ As discussed, this credit amount is based upon the amount of energy produced by alternative fuel facilities. Renewable Energy Production Credit could be applied in such a way that pharmaceutical producers would receive a tax credit to offset the costs incurred by efforts to improve production processes to prevent or alleviate a shortage. The formula will provide credits proportional to the additional drug units produced due to improved processes. By integrating the Renewable Energy Production Credit formula, pharmaceutical companies will only get the credit if their research and productive activities directly contribute to increased levels of critical pharmaceuticals. This measure will help to reduce over-production for the sole benefit of receiving the credit. Moreover, the regulation should specify that only expenses related to drugs named on FDA shortage lists could qualify for the credit;

allocation of mixed-use research expenses would be permitted.³⁴ Therefore, the credit benefit will be allowed based on the costs actually spent for investment in solving or preventing a drug shortage.

IV. CONCLUSION

Drug Shortages present a serious problem and there is an ever-increasing need for more regulatory adjustments to better combat the issue.³⁵ In an effort to encourage the pharmaceutical industry to work with the FDA to prevent and alleviate drug shortages under the newly invigorated FDASIA, joint solutions should be sought with the Treasury Department. The Treasury Department could leverage the Increased Research Credit to provide tax incentives to pharmaceutical companies to increase research related to solving drug shortages by using the same credit-calculation method as the Renewable Energy Credit.

¹ See *Regulatory Information: FDASIA*, U.S. FOOD AND DRUG ADMINISTRATION (Nov. 27, 2012), <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentstotheFDCA/FDASIA> (providing an overview of the law which amended the Federal Food, Drug, and Cosmetic Act).

² See Food And Drug Administration Safety And Innovation Act (FDASIA), PL 112-144, sec. 1001-1008, § 356 c and d, 126 Stat. 993 (2012) (defining covered drugs as those which are “life-supporting, life-sustaining; or intended for use in the prevention or treatment of a debilitating disease or condition”).

³ See Valerie Jensen, *FDA Is Asking The Public To Send In Ideas For Combating Drug Shortages*, FDA VOICE (Feb. 13, 2013), <http://blogs.fda.gov/fdavoic/index.php/2013/02/fda-is-asking-the-public-to-send-in-ideas-for-combating-drug-shortages> (noting the FDA itself can do more with help from the public).

⁴ See, e.g., *American Academy of Pediatrics – Comment*, FDA DRUG SHORTAGES TASK FORCE STRATEGIC PLAN; REQUEST FOR COMMENTS (April 2, 2013), available at <http://www.regulations.gov#!documentDetail;D=FDA-2013-N-0124-0125> (noting the serious impacts of drug shortages on the care of children).

⁵ Food and Drug Administration Drug Shortages Task Force and Strategic Plan Notice, 78 Fed. Reg. 9928-29 (Feb. 12, 2013) [hereinafter *Task Force Notice*] (calling on the public for methods to incentivize drug companies).

⁶ See 26 U.S.C. §§ 41, 45 (2010) (respectively: Increasing Research Activities Credit; Renewable Energy Production Credit).

⁷ See § 356d.

⁸ *Task Force Notice*, *supra* note 5.

⁹ *Id.*

¹⁰ See Eric Friske, Note, *Addressing Looming Prescription Drug Shortages Through Legislative and Regulatory Approaches*, 14 MINN. J.L. SCI. & TECH. 521, 539 (2013) (arguing generally that perhaps tax incentives can be used to encourage firms to maintain adequate drug levels).

¹¹ § 356c.

¹² *Id.* § 356d.

¹³ *Task Force Notice*, *supra* note 5.

¹⁴ 26 U.S.C. § 41 (2010).

¹⁵ *Id.* § 41(d).

¹⁶ *Id.* § 41(d)(2).

¹⁷ *Id.* § 41(d)(3).

¹⁸ *Id.* § 41(d)(4).

¹⁹ See generally *Tax Research: Understanding Sources of Tax Law*, CCH, http://www.cchgroup.com/opencms/opencms/web/TAA/LP/all/federaltaxlaw/DOC_Treasury-Regulations.pdf (last visited April 13, 2013) (explaining the powers of Treasury to promulgate regulations and the department's scope of authority).

²⁰ American Taxpayer Relief Act of 2012, PL 112-240, 126 Stat 2313 (2013) (extending the credit and revising portions of 26 U.S.C. § 45 (2010)).

²¹ 26 U.S.C. § 45(a) (2010).

²² See generally Mona Hymel, *The United States' Experience with Energy-Based Tax Incentives: The Evidence Supporting Tax Incentives for Renewable Energy*, 38 LOY. U. CHI. L.J. 43 (2006) (arguing how the tax credit has been an successful incentive and helped overcome the costs of complying with Congressional policy objectives by correlating the benefit with investment).

²³ *Task Force Notice*, *supra* note 5.

²⁴ See also Food And Drug Administration Safety And Innovation Act, PL 112-144, sec. 1004, § 356c, 126 Stat. 993 (2012) (mandating that the "Secretary shall maintain an up-to-date list of drugs that are determined by the Secretary to be in shortage in the United States").

²⁵ *Cf.* 21 U.S.C. § 41(d) (2010) (defining qualified research as relating to new or improved business components which could include processes designed to better manage drug supply levels).

²⁶ See generally SHEILA CAMPBELL, CONGRESSIONAL BUDGET OFFICE, Pub No. 2927, FEDERAL SUPPORT FOR RESEARCH AND DEVELOPMENT (2007) (indicating that research credits result in many benefits); DAVID H. AUSTIN, CONGRESSIONAL BUDGET

OFFICE, Pub No. 2589, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (2006) (discussing, in part, advancements in the drug industry due to congressional policy).

²⁷ See also Kreig Mitchell, *Section 41 Research and Experimentation Tax Credit Audit Considerations*, 37 COLO. LAW, Mar. 2008, at 49 (noting the legislative history; articulating incentives and importance of the credit to encourage research activities).

²⁸ *But see* § 41(d)(4) (listing excluded expenses, those for businesses components that are already commercially manufactured, or for duplication of such existing components).

²⁹ See § 41(d).

³⁰ See *id.* (excluding certain purposes for which potentially include actual costs for unit production does not explicitly prohibit expenses for improvement of such manufacturing processes, monitoring, or other costs of restarting production at the request of the FDA).

³¹ See STAFF OF H. COMM. ON OVERSIGHT AND GOVERNMENT REFORM, 112TH CONG., FDA'S CONTRIBUTION TO THE DRUG SHORTAGE CRISIS 14 (2012) (pointing to a study about the impacts of poorer quality manufacturing on drug supplies).

³² *Cf.* 26 C.F.R. § 1.41-4(c)(2)(ii) (2013) (explaining the credit in a treasury regulation that activities conducted after the components are ready for commercial sale are not permitted as qualified research purposes).

³³ See also CAMPBELL, *supra* note 26, at 27 (finding that the current method of calculation for the research credit has been criticized, noting how different formulas could encourage more research).

³⁴ See Food And Drug Administration Safety And Innovation Act, PL 112-144, sec. 1004, § 356c, 126 Stat. 993 (2012) (calling for the FDA to publish which drugs are at risk).

³⁵ See Exec. Order No. 1358876, 76 Fed. Reg. 68295 (2011) (calling on the FDA to use new approaches including examining ways to encourage improvements to manufacturing and other tools to prevent shortages by President Obama though executive order).