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March 9, 2015

Via U.S. Mail and E-mail

The Honorable Joseph R. Pitts, Chairman
Committee on Energy and Commerce
Subcommittee on Health
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for calling me to testify before the Subcommittee on Health on January 27, 2015, at the hearing "Examining Public Health Legislation to Help Patients and Local Communities." Attached to this letter are the questions for the record I received from the Honorable G.K. Butterfield and my responses to those questions. Should you or other members of the Committee have additional questions, I would be pleased to respond to those questions.

Very truly yours,

QUARLES & BRADY LLP


D. Linden Barber

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health
Adrianna Simonelli, Legislative Clerk

Attachment

DLB:rs

**“Examining Public Health Legislation to Help Patients and Local Communities”
Hearing before the House Energy and Commerce
Subcommittee on Health held on January 27, 2015**

**Questions for the Record from the Honorable G.K. Butterfield
Directed to D. Linden Barber**

Mr. Barber, we’ve heard from many people about the need to pass the Improving Regulatory Transparency for New Medical Therapies Act to expedite patient access to new medicines. Over the past 15 years, the average time to reach a DEA scheduling decision has increased dramatically.

- a) Mr. Barber, given your prior service in the DEA, what do you see as the main reason for this dramatic increase in review time?**

RESPONSE: The reasons for the increasing delay are not transparent to the public nor were they transparent to me when I was the Associate Chief Counsel at DEA. However, my experience with the Agency leads me to conclude that the primary reason for the increase in the time to schedule new molecular entities is that DEA tends to prioritize its enforcement mission to prevent diversion above its regulatory mission to ensure an adequate and uninterrupted supply of controlled medications to meet the legitimate medical needs of the United States. DEA has communicated to registrants that the Agency is first and foremost an enforcement agency, not a regulatory agency. In light of the enormous problem of prescription drug abuse, this is somewhat understandable. However, it is possible for the Agency to be both a strong enforcement agency and a responsive regulatory agency. A second reason for the increasing delays in scheduling new molecular entities is what appears to be a misunderstanding on the part of DEA about its role in scheduling these entities. The DEA is bound by the medical and scientific findings of the Secretary of Health and Human Services. DEA's role is to examine law enforcement data and information on diversion in reaching a decision about scheduling. With new molecular entities, there is no law enforcement data or history of diversion for DEA to study. Thus, there is nothing within the purview of DEA for the Agency to study that would add anything meaningful to the medical and scientific findings of the Department of Health and Human Services. Searching for law enforcement and diversion-related information on new molecular entities is futile. To the extent that DEA undertakes such queries, the Agency is unnecessarily delaying the scheduling of new molecular entities that are approved by FDA from reaching the market where patients can benefit from these products that FDA has determined are safe and effective for medical use.

- b) How often does the DEA reach a scheduling determination that differs from the FDA's recommendation and what are the leading factors that delay the Agency in making decisions?**

RESPONSE: My review of more than a decade of scheduling decisions on new molecular entities reveals that DEA has without exception adopted the FDA's scheduling recommendation on new molecular entities. The likely factors leading to the delay in DEA scheduling new molecular entities are the DEA's focus on enforcement issues rather than regulatory issues and the Agency undertaking futile inquiries which have proven to add no value to the scheduling process. These factors are discussed more fully in section a, above.

- c) Do you foresee typical circumstances that would prevent the DEA from reaching an interim scheduling determination within 45 days of the FDA's recommendation?**

RESPONSE: The only plausible explanation for DEA requiring more than 45 days to schedule new molecular entities is that the Agency must publish the proposed scheduling action in the Federal Register, provide an adequate period for public comment, and then respond to any comments in the promulgation of the Final Rule scheduling the new molecular entity. These steps are required by the Administrative Procedure Act. However, it would be feasible for DEA to publish a proposed scheduling action within five days of receiving FDA's recommendation since the proposed rules for scheduling new molecular entities are largely boilerplate proposed rules that require little original drafting by DEA. A thirty comment period is typical. Unless the Agency receives an unusual number of comments that raise complicated issues, DEA should be able to publish a Final Rule within ten days of the close of the comment period. Using the timelines above, DEA should be able to schedule new molecular entities within forty-five days of receiving FDA's scheduling recommendation.

However, this process could be even further expedited if Congress amended the CSA and directed DEA to publish its scheduling action on new molecular entities without undertaking the procedures required by the Administrative Procedure Act. The rationale for Congressional action along these lines is three-fold: 1) history indicates that DEA always accepts FDA's scheduling recommendation for new molecular entities so there is no value added in DEA delaying scheduling to undertake an independent review of the scheduling decision; 2) once FDA finds that a new molecular entity has an accepted medical use in the United States, DEA has no choice but schedule the drug in Schedule II, III, IV, or V since Schedule I drugs have no accepted medical use in the United States; and 3) DEA has emergency scheduling power under 21 U.S.C. §811(h) which would allow DEA to increase move the new molecular entity to a more restrictive schedule on an emergency basis if information

supported such an action after the substance become available to the public. Taking action to expedite the scheduling of new molecular entities would serve the both purposes of the Controlled Substances Act as reflecting in the Congressional findings of 21 U.S.C. § 801. The public would have timely access to new drugs that are helpful to American people. Meanwhile, placing new drugs in the Schedule recommended by FDA would serve to prevent the diversion and abuse of those drugs as all controlled substances without regard to the schedule of the drugs are subject to significant restrictions and if more restrictive scheduling were necessary based on an imminent hazard to public health, DEA could exercise its emergency scheduling powers.