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Lawmakers' Pressure on FDA Review of New Tobacco Products Blurs Line Between Oversight and Undue Influence

by Glenn G. Lammi

Food and Drug Administration (FDA) leadership and staff are accustomed to external criticism and pressure. After all, FDA-regulated products account for 20 cents of every dollar spent by American consumers, so criticism comes with the job. Over the past year, the volume of noise aimed at FDA over one particular duty—its review of applications for electronic nicotine delivery systems (ENDS) and other "deemed" new tobacco products—has been dialed to 11.

Pressure has come from a variety of voices and in different forms. Anti-tobacco activist groups, for example, have lobbied FDA to subject ENDS products to the new-drug approval process instead of the legislatively prescribed Premarket Tobacco Product Application (PMTA) process. FDA has thus far ignored that demand, as we discussed in our last Forbes.com commentary.

Members of Congress—several of whom co-sponsored the 2009 Tobacco Control Act—have stage-managed a pageant of outrage over ENDS that has featured committee hearings, press conferences, and information requests and letters to FDA. While those are common tools of legislative oversight, the Members' ENDS pressure campaign may have stepped over the line between oversight and impermissible interference with agency adjudication.

PMTA Process

Over the past year, the Office of Science in FDA's Center for Tobacco Products (CTP) has been reviewing over 500 marketing applications for non-combustible tobacco products. Applicants have had to submit a considerable amount of information and undergo a multi-step process to prove that their product is "appropriate for the protection of public health." Reviewers judge whether each product will increase the likelihood that current smokers will switch from combustible tobacco and decrease the likelihood that non-smokers will choose to use the ENDS product under review.

Lawmakers Get Pushy

On January 14, 2021, a group of Senators led by Majority Whip Durbin sent a pointed letter to FDA Commissioner Stephen Hahn. The Senators alleged that the agency's slow-walk of the PMTA process contributed to underage use of e-cigarettes and urged FDA to focus intently on youth use when reviewing applications. In addition to these general complaints, the letter provided FDA with a very specific "non-exhaustive list of principles that should guide FDA's review of PMTAs." Each of those four principles are introduced by the phrase "FDA should not authorize a PMTA…" Each principle demanded blanket disqualification for products that had certain characteristics, such as

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"high" nicotine content. One principle admonished FDA to look beyond general public health and ensure that an ENDS product does not disproportionately harm "vulnerable populations."[1]

A March 23 letter to Acting FDA Commissioner Woodcock headlined by Representatives Wasserman Schultz and DeGette took an equally aggressive approach, demanding several of the same categorical disqualifications as did Senator Durbin's letter. The letter went one step further, however, specifically urging FDA to reject marketing for specific manufacturers' products. During a June 23 House Oversight Subcommittee hearing at which Ms. Woodcock served as a witness, Rep. Wasserman Shultz (a non-committee member the subcommittee chairman invited to participate) pushed the Acting Commissioner to commit to using the PMTA process to reduce nicotine levels in ENDS and urged FDA to reject specific products.

In addition to Ms. Woodcock, Senator Durbin appeared as a witness at the House Oversight hearing. His prepared testimony repeated his January 14 letter's harsh criticism of FDA on underage use. He went on to demand that FDA reject "any product with a history of increasing youth use," and thundered, "It is time for FDA to be our partner in public health . . . and take these dangerous products off the market."

And just to be sure that the Acting Commissioner didn't forget what she said at the hearing, the subcommittee issued a press release not only quoting her statements, but also characterizing them in a way most favorable to the larger pressure campaign.

Finally, Senator Blumenthal chaired an August 3 Senate Commerce subcommittee hearing at which he singled out specific companies whose applications FDA should reject, and asked the witnesses to opine on how specific applications should fare.

Stepping Over the Line?

FDA and its leadership have properly refused to publicly engage with the Senators and Representatives who are lobbying them at hearings and in correspondence. To our knowledge, for instance, FDA has not responded to Senator Durbin's January 14 letter. And Acting Commissioner Woodcock deftly deflected House Oversight subcommittee members' numerous leading questions, refusing to comment on specific applicants.

But privately, it's fair to wonder how the lawmakers' pressure is *not* impacting the PMTA process. Line reviewers in the Office of Science have a great deal of discretion under the very broad public-health standard, and the constant accusations and demands by important Members of Congress could tip the balance against some approvals. And the Commissioner and other FDA leaders certainly are aware of who approves FDA's budget and votes on agency nominations.

More than just offending general notions of good-government and illegitimately attempting to impose legislative standards on FDA that Congress hasn't legislated, has the Members' pressure campaign also crossed a *legal* line? Although the caselaw on legislators' undue influence over

[1] A group of 12 eminent physicians, epidemiologists, and addiction and public-health scholars see the possible connection between vulnerable populations and non-combustible tobacco products much differently than the Senators. In an August 19 *American Journal of Public Health* article, the experts write:

> The need to pay attention to adult smokers is particularly important from a social justice perspective. African Americans suffer disproportionately from smoking-related deaths, a disparity that a new clinical trial shows, vaping could reduce. Today's smokers come disproportionately from lower education and income groups, the LGBTQ community, and populations suffering from mental health conditions and other addictions. . . . Vaping might assist more of these smokers to quit.

agency decisions is sparse, a rejected PMTA applicant might have a colorable argument that political intrusion impacted FDA's decision and thus violated the company's procedural due-process rights.

Generally, courts have undertaken deeper scrutiny of Senators' and Representatives' influence over judicial or quasi-judicial agency outcomes than their pressure on rulemaking activity. For instance, in the seminal *Pillsbury Co. v. FTC* case, the Fifth Circuit found that members of a Senate subcommittee hearing had committed an "improper intrusion into the adjudicatory process of the Commission" when chastising the FTC Chairman and his staff about developments in a Clayton Act challenge pending before the FTC. The Senators argued that FTC should have applied a stricter *per se* standard to Pillsbury's conduct in a preliminary order favorable to the company. In its final decision, the Commission applied the higher standard sought by the Senators and ruled against Pillsbury.

The Fifth Circuit reasoned:

> To subject an administrator to a searching examination as to how and why he reached his decision in a case still pending before him, and to criticize him for reaching the wrong' decision, as the Senate subcommittee did in this case, sacrifices the appearance of impartiality—the sine qua non of American judicial justice.

Pillsbury didn't need to prove that the Senators actually influenced the outcome of the FTC adjudication. The court held that in the interests of Pillsbury's due-process rights and the integrity of administrative adjudication, Pillsbury need only show the lawmakers' actions cast doubt on agency's impartiality. In post-*Pillsbury* cases where the plaintiff alleged undue influence of agency adjudication, courts have retained and applied that burden of proof.

FDA's PMTA approval process is more adjudicative than it is rulemaking. The eventual outcome, a marketing or denial *order*, arises from a formal process based on a formal record, applying legal standards set in advance on a case-by-case basis. Thus, a plaintiff suing FDA would only need to show Members of Congress's action cast doubt on the PMTA process' impartiality.

The lawmakers' pressure campaign on PMTA review featured multiple messages and messengers, as compared to the one Senate hearing in *Pillsbury*. And rather than Senators merely implying that FTC should have ruled differently in its Pillsbury case, Senators and Representatives over the past year have clearly demanded negative outcomes for specific PMTA applicants and dictated which factors should matter most during application reviews.

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For many of the PMTA applicants, an FDA denial effectively puts them out of business. That reality certainly creates a strong incentive for legal challenges. How ironic if Members of Congress's own words and deeds undo what they campaigned so aggressively for: FDA's removal of ENDS products from the market.