UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS et al.,
Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,
Defendant.

Civil Action No. 16-cv-11985-IT

PLAINTIFFS' RESPONSE TO FDA'S PROPOSED SCHEDULE
and
REQUEST FOR URGENT ACTION

This Court declared on September 5, 2018 that the Food and Drug Administration ("FDA") has both "unlawfully withheld" and "unreasonably delayed" the promulgation of a rule mandating color graphic warnings on cigarette packs and in cigarette advertising, as required by the Tobacco Control Act. Memorandum and Order ("Mem. and Order") at 1-2 [#50]. Accordingly, as required by 5 U.S.C. § 706(1), the Court found that it must compel the agency to act, and the Court ordered FDA to provide an "expedited" schedule for the completion of its rulemaking. *Id*. at 15.

Regrettably, FDA's proposed schedule shows that the agency continues to act with no sense of urgency – even while it trumpets, as it should, the massive adverse public health consequences associated with smoking and the importance of the graphic warnings Congress mandated in 2009. FDA asks the Court to allow the agency until May 2021 – more than two and one-half years from now – to submit its final rule for publication. Def.'s Statement Regarding Proposed Expedited Rulemaking Schedule ("Def.'s Proposal") at 1-2 [#53]. FDA's failure to

commit to a much swifter timetable is incomprehensible to the plaintiffs, as it should be to the Court.

In its most recent notice in the Federal Register with respect to this rulemaking, published just nine days before it submitted its proposed schedule, FDA reminded the public of the gravity and immediacy of the public health crisis that prompted Congress to enact the Tobacco Control Act and to mandate the rule which FDA is unaccountably taking so long to promulgate:

> The health risks associated with the use of cigarettes are significant and far-reaching. Cigarette smoking is the leading cause of preventable disease and death in the United States and is now responsible for more than 480,000 deaths per year. Smoking causes more deaths each year than human immunodeficiency virus, illegal drug use, alcohol use, motor vehicle injuries and firearm-related incidents combined.
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> …
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> [E]ach day in the United Sates, more than 2,300 youth under the age of 18 smoke their first cigarette, and nearly 400 youth become daily cigarette smokers. If the current trajectory of smoking rates continues, 5.6 million children alive today will die prematurely as a result of smoking.

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Cigarette Warnings, 83 Fed. Reg. 48,625, 48,626 (Sept. 26, 2018) ("Experimental Study Notice") (internal references omitted).

In spite of its recognition of the urgent need to take action to increase public awareness of the health risks of smoking, FDA has proposed to continue following a sluggish path that would end up, if accepted by the Court, with the agency promulgating a final rule more than *eight years* after the Solicitor General notified Congress in March 2013 that FDA would proceed with new rulemaking proceedings in the wake of *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205 (D.C. Cir. 2012) ("*Reynolds*"), *overruled in part by American Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). Pls.' L.R. 56.1 Statement of Undisputed Facts ¶ 32 [#29]. Even if the *Reynolds* decision made the agency's job more challenging, as FDA

suggests it did, the agency has not offered any plausible explanation of why it would take *four times* longer to complete curative rulemaking than it took the agency to promulgate its 2011 Rule – or why this Court should allow FDA to take four times longer to complete its rulemaking than Congress mandated when it passed the Tobacco Control Act.

FDA's proposed schedule confirms that only three steps in its curative rulemaking remain to be completed. As FDA acknowledges, the agency will undertake only one remaining study before it can proceed to complete its notice of proposed rulemaking ("NPRM"): what FDA calls its "second quantitative study" or "Experimental Study of Cigarette Warnings." Def.'s Proposal at 3. FDA proposes to complete this study by May 2019, seven months from now, although the agency acknowledges that the required data gathering (which is the subject of its recent Experimental Study Notice) can be completed in just fifteen days. *Id*. at 5, n.2. Despite the fact that FDA has spent the past five years developing and testing alternative textual warnings and developing and testing new graphic warning images, FDA next proposes to take an additional eleven months after completing its final study – until April 2020 – to finish preparing its NPRM and submit it for publication. *Id*. at 2. The agency took only seventeen months after enactment of the Tobacco Control Act, working from scratch, to set up the Center for Tobacco Products; design, study and test graphic warnings; and prepare the NPRM published in October 2010. Required Warnings for Cigarette Packages and Advertisements; Proposed Rule, 75 Fed. Reg. 69,524 (Nov. 12, 2010) ("2010 NPRM"). FDA then proposes to take an additional thirteen months after publishing its NPRM – until May 2021 – to review public comments and publish its final rule, even though the agency was able to submit its 2011 Rule just seven months after publishing its 2010 NPRM. Required Warnings for Cigarette Packages and Advertisements; Final Rule, 76 Fed. Reg. 36627 (June 22, 2011) ("2011 Final Rule"). The FDA's proposed

timetable cannot reasonably be called an "expedited" schedule, and it should be flatly rejected by the Court.

FDA claims its original schedule, submitted to the Court in May 2017, was "already compressed" and pats itself on the back for having shaved off all of two months in its proposed "expedited" schedule, so that on its proposed timetable, the final rule would now be published by May 2021, rather than by July 2021. Def.'s Proposal at 2. FDA has offered no basis, other than self-serving proclamations, for the Court to find that FDA's proposed schedule is "the most aggressively expedited yet achievable schedule" or that it allows for "the absolute lowest" or "bare minimum" amount of time the agency would need to complete the rulemaking "in accordance with the law and FDA's public health mission." *Id*. at 6, 8.

FDA asks the Court to defer to its judgment about how much time is needed to complete its pending rulemaking, citing *NRDC v. FDA*, 884 F.Supp.2d 108, 121 (S.D.N.Y. 2012). Def.'s Proposal at 8. In that case, the court imposed a firm deadline for agency action, over FDA's objection, to correct FDA's "misprision of its duty" to initiate congressionally-mandated proceedings. *Id*. at 119. While the court elected to rely upon FDA's analysis of how much time it would reasonably take FDA to complete its work, in that case FDA offered expert testimony detailing what the agency itself would have to do. *Id*. at 121. Here, in contrast, FDA attempts to justify much of its dilatory schedule on the basis of anticipated delays in bureaucratic review that can be avoided – or dramatically reduced – if this Court arms FDA with a series of court-ordered deadlines that the agency must meet. Specifically, FDA's proposed timetable overlooks the opportunities the agency has to accelerate review of its work within its own Department of Health and Human Services ("HHS") and at the Office of Management and Budget ("OMB"); to use its expansive resources to jumpstart most of the NPRM long before its final quantitative

study is finished; and to move swiftly to a final rule after soliciting and reviewing public comments.

Where, as in this case, "an agency has failed to meet the statutory deadline for a nondiscretionary act, the court may exercise its equity powers 'to set enforceable deadlines of both an ultimate and an intermediate nature.'" *Sierra Club v. Johnson*, 444 F. Supp. 2d 46, 52-53 (D.D.C. 2006) ("*Johnson*"), quoting *NRDC v. Train*, 510 F.2d 692, 705 (D.C. Cir. 1974). *See Oxfam America, Inc. v. United States Sec. & Exch. Comm'n*, 126 F. Supp. 3d 168, 176 (D. Mass. 2015) (retaining jurisdiction to monitor the schedule and ensure compliance with Court's order). An agency proposing a schedule in this context – where a statutory deadline has been missed by many years – must demonstrate that the agency "has in good faith employed the utmost diligence in discharging his statutory responsibilities." *Johnson*, 444 F. Supp. 2d at 52-53. This Court has already found that FDA has not done so. Mem. and Order at 15. When the Court considers FDA's proposed schedule, it should "separate justifications grounded in the purpose of the Act from the foot-dragging efforts of a delinquent agency." *Johnson*, 444 F. Supp. 2d. at 53, quoting *Train*, 510 F.2 at 713. As the Court has already found, FDA cannot justify its delay on the basis of inadequate resources or competing agency obligations, Mem. and Order at 2, n.2 & 14, and FDA does not attempt to do so. FDA has a "heavy burden" to show that its proposed schedule is as expedited as it could possibly be, and "[t]hat burden is especially heavy where the agency has failed to demonstrate any diligence whatever in discharging its statutory duty to promulgate regulations and has in fact ignored that duty for several years," as FDA has in this case. *Johnson*, 444 F. Supp. 2d at 53-54 (citations omitted). *See Community In-Power & Dev. Ass'n, Inc. v. Pruitt*, 304 F. Supp. 3d 212, 222 (D.D.C. 2018) ("the applicable standard is impossibility" and the EPA "has failed to demonstrate that it would be impossible for the agency to follow a

more expeditious schedule than the one that it proposes"). The schedule proposed by FDA does not remotely begin to meet this standard.[1]

The plaintiffs propose that FDA be ordered to complete its "Experimental Study of Cigarette Warnings" no later than February 28, 2019; to submit for publication its NPRM in the Federal Register by June 30, 2019; to complete the review of public comments by October 31, 2019; and to submit for publication its final rule in the Federal Register no later than January 31, 2020.[2] FDA has already been at work on its new rule for five and a half years, and there is no reason for the Court to find that the agency needs any more time to complete its current rulemaking than the plaintiffs propose. As FDA tacitly admits, the entry of a court-ordered timeline will allow FDA to accelerate OMB review of its proposed study, its NPRM and its Final Rule and will make it possible for FDA to complete its rulemaking far more swiftly than FDA has proposed. *See* Def.'s Proposal at 4, n.1.

Completion of Research to Support the Rule

FDA acknowledges that since the Court heard oral argument on the cross-motions for summary judgment on January 24, 2018, FDA has completed its final qualitative study of new graphic warning images (what FDA has called "step (g)") and its initial quantitative study ("step

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[1] The Regulatory Information Service Center of OIRA in the OMB compiles a semi-annual Unified Agenda of Federal Regulatory and Deregulatory Actions that presents agency statements of regulatory priorities and additional information about significant regulatory activities planned for the coming year. In April 2017, the graphics warning rule was not listed as an agency priority on FDA's "Unified Agenda," and curiously, even after this Court's September 5, 2018 Order, the graphics warning rule does not appear on OMB's Fall 2018 Unified Agenda or its list of Current Long Term Actions. *See* HHS's Statement of Regulatory Priorities for Fiscal Year 2019, available at https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/201810/Statement_0900.html; HHS/FDA's Long-Term Actions Rule List, available at https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPubId=201810&showStage=longterm&agencyCd=0900. This is so despite the fact that the Unified Agenda lists other NPRMs planned for issuance as late as December 2020 (for example, the NPRM for Acute Toxicity Warnings for E-Liquids, 0910-AH24, is scheduled for issuance in December 2020). FDA's failure to include the rule in these lists demonstrates that the agency continues to treat the rule with no sense of urgency, even after the Court's order.

[2] Even if the Court were to adopt the plaintiffs' proposed schedule, and FDA were to adhere to it, the new graphic warnings rule would not take effect until May 1, 2021 because the Tobacco Control Act provides in § 201(b) that the graphic warnings rule will not take effect for 15 months after it is promulgated.

(c)"). Def.'s Proposal at 3. FDA received the final reports of each of these two studies by the beginning of May 2018. *Id.* The agency, however, has continued to work at a "business as usual" pace. After receiving the results of these two studies, it took FDA three months to digest the results and lay the groundwork for the only study that remains before FDA can finish its NPRM: the second quantitative study, the "Experimental Study of Cigarette Warnings." *Id.* Apparently believing that it was required to follow "normal clearance procedures" under the Paperwork Reduction Act ("PRA") before it could begin data collection under this study, FDA inexplicably spent two months drafting the routine, three-page Federal Register notice required by the PRA. *Id.* at 4 & n.1; *see* 83 Fed. Reg. 48,625-48,628.

FDA continues to act as if it is under no statutory duty to expedite its rulemaking. FDA acknowledges that the data collection contemplated by its "Experimental Study of Cigarette Warnings" can be completed in "approximately 15 days," Def.'s Proposal at 5, n.2, but the agency asks the Court to allow FDA until May 2019 – seven months from now -- to complete this study. Some of this time is presumably required for the preparation of a report on the study results, but it is evident from FDA's submission that the agency expects the bulk of this time to be consumed by review of the proposed data collection by the OMB under the PRA. FDA assumes that it is "*currently*" required to "follow the standard PRA procedures for review and approval" by the OMB under the PRA. Def.'s Proposal at 4, n.1 (emphasis supplied). But FDA acknowledges, as it must, that under the PRA the "normal clearance procedures" can be set aside when swifter action is required to comply with a statutory or court-ordered deadline. *Id.*

The PRA lays out a time-consuming sequence of public notices and agency reviews that must ordinarily be completed before the OMB approves or disapproves a proposal by an agency such as FDA to collect data from the public. See 44 U.S.C. §§ 3506 & 3507. These are the

"normal clearance procedures" to which FDA refers. Def.'s Proposal at 4, n.1. As the plaintiffs pointed out at the summary judgment hearing and in their February 2, 2018 Response to FDA's Supplemental Filing [#49], however, the PRA anticipates and provides for accelerated review when needed by an agency to comply with a statutory or court-ordered deadline. The statute explicitly authorizes the head of an agency to request OMB to authorize a collection of information without complying with normal clearance procedures if "*the use of normal clearance procedures is reasonably likely to . . . cause a statutory or court ordered deadline to be missed*." 44 U.S.C. § 3507(j)(1)(B)(iii) (emphasis added). If such a request is made, OMB "shall approve or disapprove any such authorization request within the time requested by the agency head." 44 U.S.C. § 3507(j)(2).

In accordance with this statutory authority, the Administrator of OMB's Office of Information and Regulatory Affairs ("OIRA") advised the heads of all Federal departments and agencies, presumably including both HHS and FDA, "how they can receive expedited clearance for information collections in certain situations." Memorandum of Howard Shelanski, Administrator, Office of Information and Regulatory Affairs (July 22, 2016) ("OIRA Notice") at 1, available at https://obamawhitehouse.archives.gov/sites/default/files/omb/inforeg/pra_flexibilities_memo_7_22_16_finalI.pdf. Notably, the OIRA notified all Federal agencies that they could seek "emergency review" when necessary to comply with a statutory or court ordered deadline:

> OIRA may grant expedited review if the collection is essential to the mission of the agency, clearance is needed sooner than the normal timeframe, and the agency cannot reasonably comply with the PRA's normal clearance procedures because: (1) public harm is reasonably likely to result if normal clearance procedures are followed; (ii) an unanticipated event has occurred; or (iii) the use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information or *is reasonably likely to cause a statutory or a court ordered deadline to be missed*. When OIRA expedites review, OIRA acts promptly to

> review the [information collection request] through a suitably streamlined process, consistent with the purposes of the Paperwork Reduction Act.

Id. at 5 (emphasis added). Thus, under the plain language of the PRA and the guidance given by the OIRA, the timing of OMB approval to undertake the "Experimental Study of Cigarette Warnings" is in FDA's hands. FDA has acted throughout the pending rulemaking as if it were unaware of this opportunity.

FDA could have and should have invoked the emergency provisions of the PRA long ago, when it sought OMB approval for its "final qualitative test of images" ("step(c)") and its "initial quantitative test) ("step (g)"). But instead FDA went through OMB's time-consuming normal clearance procedures. First Supp. to Def.'s L.R. 56.1 Statement of Facts [#42].[3] FDA could have and should have also sought a waiver of the PRA's public comment requirements before it published its recent notice in the Federal Register with respect to its upcoming "Experimental Study of Cigarette Warnings."

OIRA explicitly notified all Federal agencies that, when necessary to meet a statutory or court ordered deadline to be missed, "OIRA may modify – or, if necessary, *waive* – the public comment requirements" of the PRA. OIRA Notice at 5 (emphasis added). Had FDA taken advantage of this advice, the agency could have sought a waiver of the currently pending 60-day public comment period that the FDA commenced on September 26, 2018 – three weeks after the Court ruled against the agency and ordered FDA to propose an expedited schedule.

OIRA would have no good reason to deny such a waiver, given this Court's finding that FDA has failed to comply with the statutory deadline set by the Tobacco Control Act and given

[3] FDA now ascribes "a previous four-month delay in its project deadlines" to "events affecting the research program." Def.'s Proposal at 2. What FDA does not say, however, is that this delay was attributable to prolonged OMB review of these two previous studies that FDA could have avoided either by invoking the non-response mechanism in the PRA allowing FDA to "infer" OMB approval, *see* Mem. and Order at 12, or by seeking expedited OMB approval in light of the statutory deadline imposed by the Tobacco Control Act.

that in this case, FDA proposes to gather information from *volunteers* who will participate in a short, three-stage online survey. This sort of data collection does not implicate the interests the PRA was designed to protect. The PRA's purpose was to minimize intrusive governmental inquiries and eliminate unnecessary gathering of information from the public. *See Dole v. United Steelworkers of Am.*, 494 U.S. 26, 32-33 (1990).

While it may be too late to rescind the public notice FDA improvidently published on September 26, 2018, there is no reason why FDA could not, right now, ask OMB to waive the subsequent 30-day public comment period FDA anticipates. *See* Def.'s Proposal at 4-5. FDA's persistent failure to invoke available tools to expedite its long-overdue graphic warnings rule underscores the need for the Court to impose an expedited schedule. *See Sierra Club v. Johnson*, 2011 WL 181097 at *9 (D.D.C. 2011) (agency had "engaged in discretionary delay in the face of a congressional directive" when it "failed to ask OMB to expedite its review" of the agency's information collection request under the PRA, "when the normal review process '[was] reasonably likely to cause a statutory or court-ordered deadline to be missed.'").

FDA continues to act as if there is no applicable statutory deadline, even though this Court found "it cannot be the case that the FDA has freed itself from Congressional mandates and may now take the opportunity to promulgate this rule at whatever pace it chooses." Mem. and Order at 10. As the Court has already determined, the vacatur in *Reynolds* "reset the two-year clock"; it did not "negate the FDA's continuing obligation to comply with Congress' deadlines." *Id*. Neither that ruling nor the Court's clear signal at the summary judgment hearing that "court intervention may well be necessary," Oral Arg. Tr. at 59 [#47], appear to have been enough to spur FDA into seeking expedited OMB review. It is obvious that unless the Court promptly and explicitly orders FDA to complete the "Experimental Study of Cigarette

Warnings" by a fixed deadline, the agency will make no effort to take advantage of the provisions of the PRA that were designed to allow for expedited OMB review in circumstances exactly like these. The Court should order FDA to complete its "Experimental Study of Cigarette Warnings" no later than February 28, 2019.

Completion of the NPRM and Final Rule

Even on this schedule, by the time FDA has the results of its final study and is poised to complete the preparation of its proposed rule, the agency will already have taken nearly six years to develop a new graphic warnings rule after deciding not to seek review of the *Reynolds* decision. In light of all the work the agency has already completed – including the development and assessment of new textual warnings (a detour not required by *Reynolds*) and the creation and testing of new graphic images, FDA's assertion that it will take an additional eleven months to complete its proposed rule and prepare the NPRM is difficult to take seriously. The agency should have begun the preparation of the proposed rule and NPRM long ago – and the plaintiffs presume they did so. While the results of its pending "Experimental Study of Cigarette Warnings" undoubtedly will inform FDA's choice of the textual and graphic warnings it will mandate, these results are unlikely to change the framework of the new rule or the extensive discussion FDA will offer in the NPRM of the underlying public health crisis, the regulatory history, and the efforts the agency has made since *Reynolds* to develop a new rule that will withstand judicial review (including the development and results of all the studies the agency has already completed).

FDA does not claim that it needs eleven months just to "analyze the results of the final study and deliberate with science, policy, and legal staff and government officials to determine the scope and contents of the proposed rule." Def.'s Proposal at 6. The plaintiffs do not dispute

FDA's need to complete that work (although FDA should be poised to do so quickly after it receives the results of its final study), but FDA never says how much time it will need to do it. Instead, FDA lays much of blame for its prolonged schedule for publishing the NPRM – and then, after reviewing public comments, for promulgating its final rule – on the need for "review and clearance within FDA and the Department of Health and Human Services," followed by "centralized review" by the OMB as purportedly required by Executive Order 12866. Def.'s Proposal at 5-7 & n.3.

This Court should not indulge FDA's request for much time so that it can work through whatever bureaucratic logjams the agency anticipates *within HHS*. FDA acknowledges that it has already discussed the Court's September 26, 2018 Order with all the agencies and offices involved in the rulemaking, and FDA reports that they all understand that the "Court intends to direct further action, as necessary, following review" of FDA's proposed schedule. Def.'s Proposal at 4, n.1. FDA has assured the Court that it "will keep all involved in the rulemaking abreast of the Court's further rulings in this case." *Id*. at 5. It is not enough for FDA to promise the Court it will "seek collaboration for prompt review." *Id*. FDA has a nondiscretionary legal duty to promulgate the new graphics warning rule, and this Court should compel FDA to publish its NPRM, and then its Final Rule, on a timetable that allows little time for the agency to complete whatever review it needs within HHS. FDA has not pointed to a single case in which a court, faced with an agency's long-standing failure to comply with a statutory deadline, has made allowance for protracted intra-departmental review. FDA has it backwards: whatever intra-departmental review is required must be tailored to the schedule the Court orders, not the other way around.

This Court should also give little, if any, weight to FDA's perceived need for OMB approval. OMB review of FDA's proposed and final rules is not required by any statute. Rather, as FDA concedes, OMB review of proposed rules is only required by Executive Order 12866, 58 Fed. Reg. 190 (Oct. 4, 1993). *See* Def.'s Proposal at 5, n.3. The need for OMB review, however, cannot excuse FDA from meeting statutory deadlines or court-ordered timetables imposed to ensure compliance with a statutory mandate. The reason is simple, as the United States Court of Appeals for the District of Columbia Circuit has held: "needless to say, the President is without authority to set aside congressional legislation by executive order, and the 1993 executive order does not purport to do so." *In re United Mine Workers of America Intern. Union,* 190 F.3d 545, 551 (1999). *Accord In re Paralyzed Veterans of America,* 392 F. App'x 858, 860-61 (Fed. Cir. 2010) (when Congress sets a deadline for promulgating a regulation, "Congress has effectively altered the agency's discretion and 'required by law' that the final rule be published notwithstanding the deadlines that appear in the Executive Order for action by OMB."); *American Lung Ass'n v. Browner,* 884 F. Supp. 345, 349 (D. Ariz. 1994) ("Review by the [OMB] serves no congressional purpose and is wholly discretionary. Therefore, it is not required, and the schedule shall exclude such review.").[4]

Although FDA makes no mention of it, much like the PRA, Executive Order 12866 anticipates in Section 6(a)(3)(D) the need for expedited review "when an agency is obligated by law to act more quickly than normal review procedures allow." Section 6(a)(3)(D) explicitly provides that when, as here, regulatory action "is governed by a statutory or court-imposed

[4] Various courts reached the same result when considering an earlier Executive Order, which, like Executive Order 12866, called, in normal circumstances, for OMB review of proposed and final reviews, but which, also like Executive Order 12866, exempted rules from OMB review when necessary to comply with statutory and court-ordered deadlines. *See, e.g., Natural Resources Defense Council v. EPA*, 797 F. Supp. 194, 197 (E.D.N.Y. 1992) ("OMB's review of the draft proposed regulations does not at all justify EPA's delay."); *Environmental Defense Fund v. Thomas*, 627 F. Supp. 566, 571 (D.D.C. 1986) ("if a deadline already has expired, OMB has no authority to delay regulations subject to the deadline in order to review them under the executive order.").

deadline," the agency must notify OIRA "as soon as possible" and must, "*to the extent practicable,* schedule rulemaking proceedings so as to permit sufficient time for OIRA to conduct its review" (emphasis added). Section 8 of the Executive Order underscores that its normal pre-publication review requirements are inapplicable "to the extent required by law," and Section 9 provides that "nothing in this order shall be construed as displacing the agencies' authority or responsibilities as authorized by law." Thus, the Executive Order itself contemplates that whatever OMB review occurs must take place on whatever timeline is ordered by the Court. The Executive Order itself thus provides no basis for granting FDA any additional time to complete its rulemaking.

The Court should order FDA to submit for publication its NPRM in the Federal Register by June 30, 2019. By that time, FDA will have had four months to incorporate the results of its final study in the proposed rule and the explanatory information FDA will offer in its NPRM. FDA has had many years to prepare the bulk of the other material that will appear in its NPRM.

The Court should order FDA to complete its review of public comments submitted in response to the NPRM by October 31, 2019. The NPRM will allow 60 days for comments, and FDA has pledged to assign staff with relevant experience to begin to review comments, and draft responses, as soon as the comments are received. Def.'s Proposal at 6-7. There is no reason why FDA cannot complete its review of comments four months after publishing its NPRM.

The Court should order FDA to publish its final rule in the Federal Register by January 31, 2020. By its own account, FDA was able to digest more than 1,700 comments and move from its 2010 NPRM to the 2011 Final Rule in just seven months. Def.'s Proposal at 7. The plaintiffs propose to allow the agency seven months for this final phase: four months for notice and comment (June 30 to October 31, 2019) and then three more months to complete the final

rule. There is no good reason for the Court to give FDA thirteen months to proceed from NPRM to final rule, as the FDA proposes. Seeking to justify its proposal, FDA points to "the required review and clearances" within HHS and at OMB it foresees after its review of public comments and drafting of the final rule have been completed. Def.'s Proposal at 7. But these requirements can be adjusted, if necessary, to meet the deadlines the plaintiffs propose if they are included in a court-ordered timetable for the completion of FDA's rulemaking.

Plaintiffs' Proposed Schedule

For all of these reasons, the plaintiffs respectfully ask the Court to reject FDA's proposed schedule and, instead, enter an order:

1. Requiring FDA to comply with the following deadlines:

"Experimental Study of Cigarette Warnings" to be completed by February 28, 2019
NPRM to be submitted for publication in the Federal Register by June 30, 2019
Review of public comments to be completed by October 31, 2019
Final Rule to be submitted for publication in the Federal Register by January 31, 2020;

2. Requiring FDA to notify the plaintiffs no later 45 days before each of these milestones if at that time FDA has any reason to believe that it will be unable to comply with a court-ordered deadline; and

3. Retaining jurisdiction to enforce FDA's compliance with the Court's order.

Request for Urgent Action

The plaintiffs also respectfully urge the Court, as soon as possible, to establish firm deadlines for FDA's completion of each of the remaining steps of its rulemaking. FDA's track record proves that the agency will not act as if there is a deadline unless the Court enters such an order, but once the Court does so, the FDA can (and presumably will) point to the court-ordered timetable as requiring expedited review by OMB and within HHS. The Court can, in this way,

both enable and compel FDA to expedite the promulgation of this critically important public health regulation.

Respectfully submitted,

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Certificate of Service

I hereby certify that this document filed through the ECF system was sent electronically to all counsel of record on October 17, 2018.

/s/ Jessica A. Wall