February 5, 2018

Re: Public Comment Regarding: Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration, Docket No. FDA-2017-N-5093

The undersigned organizations represent consumer and public health interests and comment as follows regarding the proposed deregulatory initiative at the Food and Drug Administration (FDA).

FDA regulations play a crucial role in protecting public health nationwide. Regulatory oversight of food, pharmaceutical products, and medical devices allows us to trust consumer products and avoid preventable injuries and illnesses. By protecting public health and safety, FDA contributes to healthy lives and a healthy national economy.

It is with this context in mind that we submit these public comments on the FDA request for information titled "Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration."

In undertaking its review of regulations, we strongly urge FDA to prioritize only those deregulatory proposals that offer a concrete, evidence-based benefit to public health or address part of a rule that demonstrably impedes safety or public health, or progress on public health or safety. Expending any agency resources on deregulatory initiatives can be justified only if the deregulatory action benefits public health, safety, or transparency in the marketplace. The effort would otherwise would not be in keeping with the agency's organic statute, delegated authority, and mission.

The E.O. 13771 requirement to eliminate existing regulations in order to adopt new ones imperils FDA's ability to meet its Congressionally mandated responsibilities. FDA must not allow this requirement to interfere with carrying out its mission or following required agency procedures. Just as when it promulgates a new regulation, an agency's actions to rescind or modify regulations are subject to administrative and substantive statutory obligations. This requires that the agencies engage in reasoned decision-making, informed by input from the public, to interpret the laws and assess how best to execute the authority granted them by Congress.

Although executive orders may, within limits, be used to set policy for agencies regarding rulemaking, E.O. 13771 does not supersede those requirements. In acting on E.O. 13771 or 13773 (or otherwise taking regulatory or deregulatory action), FDA must adhere to the requirements of the APA; the tenets of reasoned decision-making, including consideration of a regulation's benefits; and Congressional directives. As Lisa Henzerling notes in a forthcoming law review article:[1]

> [J]ust as "the powers of the legislature are defined and limited," so, too, are the powers of the "modern administrative state."[2] An agency is, as the courts have reminded us, a "creature of statute,"[3] with "literally … no power to act, unless and until Congress confers power upon it."[4] An agency's action "cannot stand" if there is no statutory authorization

for it.[5] Most important for present purposes, an agency has no "inherent" (non-statutory) authority to delay or suspend rules while it reconsiders them.[6]

The comments below outline key principles that should guide FDA in considering each regulation for repeal, rescission, or modification as a part of the E.O. 13771 regulatory review. In sum, this review should not serve as an opportunity for industry to hobble or remove regulatory initiatives that protect the public, but instead must be a good-faith effort that prioritizes public health and safety.

Overarching Principles: Any Deregulatory Activity Must be Lawful, Advance the Agency's Mission and Be Justified by a Current Record

1. Any agency resources expended on deregulatory initiatives are justified only if the deregulatory action benefits public health, safety, or transparency in the marketplace. The effort would otherwise would not be in keeping with the agency's organic statute, delegated authority, and mission.

2. The agency should therefore prioritize only those deregulatory proposals that offer a concrete, evidence-based benefit to public health or that address part of a rule that either demonstrably impedes safety or public health or interferes with progress on public health or safety.

3. The comment intake format that FDA proposed should be adjusted to clearly indicate that FDA must provide, for each proposal, a fair and balanced assessment of the value to and for the public of any agency investment of time and resources in this effort. Nor should resources spent on deregulation be permitted to derail the agency's considerable regulatory agenda and plans.

4. Before considering deregulation on the basis of reported burdens, the agency must issue a request for data substantiating the claims of industry as to burdens of the relevant regulation. Mere assertions regarding the burden on industry are a patently insufficient basis on which to undertake deregulation. We further note that industry's specific recommendations are non-binding and are mere reflections of industry viewpoints.

5. Deregulation is a form of regulatory action equal to regulation under the APA and must be attended by a similar process (including regulatory impact evaluations and full notice and comment procedures with adequate time for public input) under the law.

6. When considering any deregulatory action, foregone benefits to the public from any deregulatory action must be counted as costs to the public.

7. Costs of regulatory compliance are highest when rules are first promulgated and decline substantially in later years. Therefore, any proposed deregulatory action must be based on data that are current and reflected as a distinct cost in present business terms and practice, not merely a reflection of past Regulatory Impact Analyses (RIAs) or prior analyses on anticipated costs.

8. Regulations form an intricate fabric. They are constructed with substantial public input from a variety of stakeholders, and are often adjusted as they are developed to reflect the logic of prior agency decisions and actions; thus, duplication and logical gaps are not as common as the notice suggests.

9. Moreover, many rules involve staggered compliance deadlines, carve-outs, or waivers, and reflect prior compromises on feasibility and goals that already accommodate industry burdens and cost concerns, particularly following OMB/OIRA involvement and review. These decisions should not be re-litigated; thus, if an alternative was considered and rejected as part of the RIA, the agency should not spend time and energy on a renewed consideration of that alternative.

10. Where evidence of either benefits or burdens of a current rules is limited, or of insufficient quality, given the outlay of public resources, the agency's default should be to retain the regulation.

Many regulations benefit industry as well as the public by creating public confidence in the marketplace and consumer goods and ensuring that the costs for public health and safety are not a focus of market competition. Both the measurable and the intangible benefits of a fairly and publicly regulated marketplace must be valued and fully considered when contemplating deregulation, in addition to calculating any direct regulatory costs related to a particular rule. Gaps in data are cause for caution in removing regulations.

In response to the questions posed in Docket No. FDA-2017-N-5093, we provide these comments as guidance for evaluating comments and evidence submitted for this regulatory review.

1) Is the regulation still current, or is it outdated or unnecessary in some way?

- If an agency has pursued prior enforcement actions based on a regulation, that should be viewed as *prima facie* evidence that it is not obsolete.
- Mere clarification of a prior rule through guidance is not evidence of duplication or redundancy.
- Any rescission of a rule for obsolescence or duplication should be as narrowly crafted as possible to achieve its goals.
- Wherever there may be partial or full redundancy, the rule that is more protective of public health should remain in force.
- Where possible, agencies should ensure that industry, as the primary beneficiary of such actions, bears responsibility for any efforts to keep rules up-to-date. For example, CFSAN could require filings every five years regarding all substances used in food, and approvals for any substances with no reported use in the past five years could be rescinded summarily.
- If the agency does not provide sufficient evidence of a regulation being outdated, including evidence that public health will not be harmed by its alteration or removal, then the assumption of outdatedness is unfounded.

2) *Have regulated entities had difficulties complying with the regulation?*

Look-back economic studies of regulatory costs demonstrate that the cost-effectiveness of rules is often understated at the time of proposal and promulgation.

i. An example is the Physician Payments Sunshine Act: Industry initially decried new reporting and costs, but after they realized the medical community was on board, industry then spent money to comply long before the legislation passed. They later complained that if the Sunshine Act did not become law, they would have lost millions in preparation. The pre-law complaints and predictions that doctors would stop taking such payments if they were public were wrong. The law works as intended; the public has online access to the payments by drug and medical device industry to doctors and surgeons, and the medical professionals are still receiving these monies unabated and unrestricted, except the payments are now public for patients and consumers to view for free.

- Instead, regulatory costs are often transient marketplace adjustments, or factored into compliance time-frames that substantially reduce, if not eliminate, burdens.
- Cost and burden analysis cannot therefore be measured on the basis of the RIA or rulemaking prognostications.
- Thus, industry must demonstrate that specific costs or burdens related to the rule persist to the present day and have not been otherwise merely factored in the overall costs of doing business.
- Moreover, industry must demonstrate why flexibility on program administration, enforcement (*e.g.*, compliance waivers), compliance deadlines or other aspects of agency administration of the rule have not reduced the burden in question.
- If the rule delivers substantial social benefit and those exceed the burden, it should be retained.
- In addition, foregone benefits to the public from any deregulatory action must be counted as costs to the public.

3) *Does the regulation impose requirements that are also provided for in voluntary or consensus standards or guidance by third-party organizations (e.g., International Council for Harmonization, International Organization for Standardization, Codex Alimentarius)?*

- Under the National Technology Transfer Advancement Act, agencies already routinely consider third-party standards in developing regulations. This question is therefore unlikely to elicit much information not already considered during rulemaking.
- The trade standards referenced by the agency have limited applicability in many contexts, and in most cases do not directly apply as standards in the domestic context. Domestic entities are unlikely to retain the records needed to show compliance, as the

standards typically lack an enforcement mechanism and do not supersede or render irrelevant domestic rules.

- It would be needlessly complex and inordinately difficult in many cases to measure whether an international regime provides more or less public health protection than a domestic scheme.
- Where an international approach does offer clear public health benefits over that achieved in the U.S. under domestic law, FDA should consider its merits. Rule harmonization should never undermine current standards.

4) *Does the regulation contain redundant, outdated, or unnecessary collections of information or retention of records, e.g., reporting, recordkeeping, or labeling requirements?*
   - Where recordkeeping is required, it is frequently under FDA's umbrella authority because the records are essential to providing enforcement capacity to fulfill FDA's delegated authorities.
   - Existing administrative procedures already allow multiple opportunities for redundant and unnecessary information collections or recordkeeping requirements to be identified and remedied. Before any deregulatory actions are undertaken in response to this question, FDA must demonstrate that the complaint was not considered in earlier rulemaking.

5) *Could the goal of the regulation be achieved by less costly means that would provide the same level of public health protection?*
   - Industry must provide, in full and for public examination, evidence the that the level of public health protection would be the same or better following alteration of a rule on these grounds.
   - The rulemaking process includes opportunities for stakeholders to propose alternatives, which agency staff consider. As stated in the principles above, industry should be expected to demonstrate that its preferred approach was NOT already considered and rejected by the agency, and FDA should not reconsider changes that were previously rejected. Many rules involve staggered compliance deadlines, carve-outs, waivers and reflect prior compromises on feasibility and goals that already accommodate industry burdens and cost concerns, particularly following OMB/OIRA involvement and review. These decisions should not be re-litigated; thus, if an alternative was considered and rejected as part of the RIA, the agency should not spend time and energy on a renewed consideration of that alternative.

6) *What factors should FDA consider in selecting and prioritizing regulations and reporting requirements for reform?*
   - Public health and safety should be the most important and overriding factor.
   - Rules should not be considered for change unless such changes offer benefits to the public and do not increase risks to public health and safety.

- The burden of the evidence for justifications for changes to rules rests with those proposing the changes rather than FDA, and must be fully and publicly demonstrated. Where anticipated public benefits are limited or not sufficiently supported by evidence, the agency should maintain the status quo.

Conclusion: FDA Should Prioritize Public Health as Its Mission Requires

In its regulatory review process, we strongly urge the Food and Drug Administration to focus on how the agency can improve its performance, including its central mission of protecting the public health by ensuring safety and advancing public health.

For additional information, please contact the undersigned organizations:

Association of Reproductive Health Professionals
Center for Science in the Public Interest
Consumer Federation of America
In Our Own Voice: National Black Women's Reproductive Justice Agenda
Jacobs Institute of Women's Health
National Center for Health Research
National Institute for Reproductive Health (NIRH)
National LGBTQ Task Force
National Partnership for Women & Families
National WIC Association
Union of Concerned Scientists

Notes

[1] Heinzerling, Lisa, *Unreasonable Delays: The Legal Problems (So Far) of Trump's Deregulatory Binge*, Harv. L. & Policy Rev. (forthcoming 2018).
[2] *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 1995).
[3] *Atlantic City Elec. Co. v. FERC*, 295 F.3d 1, 8 (D.C. Cir. 2002); *Soriano v. United States*, 494 F.2d 681, 683 (9th Cir. 1974); *Hi-Craft Clothing Co. v. NLRB*, 660 F.2d 910, 915 n. 3 (3d Cir. 1981).
[4] *Louisiana Public Service Comm. v. FCC*, 476 U.S. 355, 374 (1986).
[5] *Michigan v. EPA*, 268 F.3d at 1081.
[6] *NRDC v. Abraham*, 355 F.3d 179, 202 (D.C. Cir. 2004).