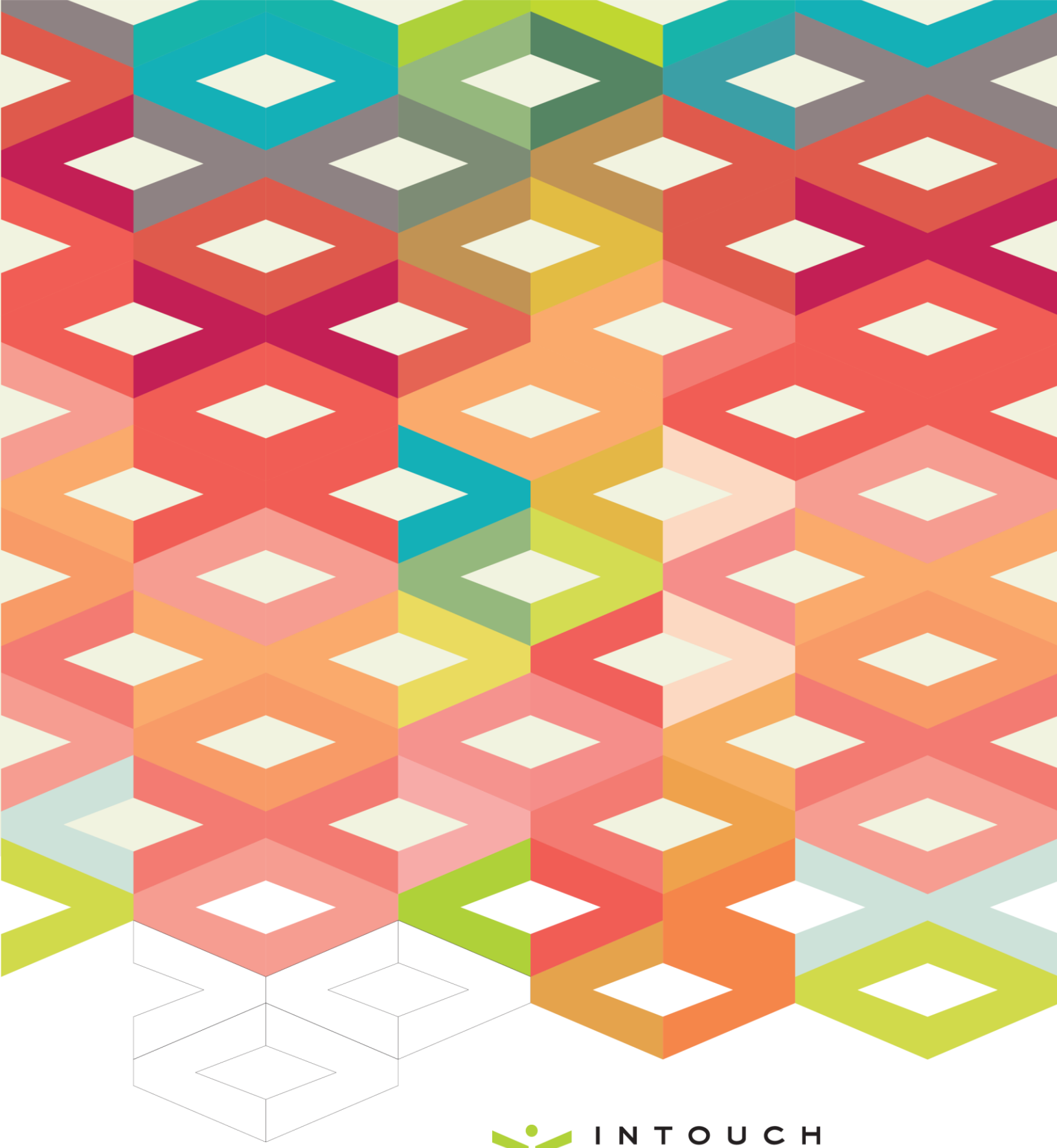

INTOUCH SOLUTIONS®

POV: NEW ADMINISTRATION IMPACT ON THE FDA

JANUARY 2017

NEW ADMINISTRATION IMPACT ON THE FDA

EXECUTIVE SUMMARY

The first 12 days of the new administration have seen a flurry of activity from the Oval Office. Some of these actions will have direct impacts on the pharmaceutical industry and the marketers of prescription drugs, devices, biologics and vaccines. Specifically, three early Trump executive orders are likely to have significant effects on the ability of the Food and Drug Administration (FDA) to provide Industry with guidance and a stable regulatory framework. This POV summarizes the orders and looks at the possible effects they will have on the pharma industry.

KEY FEATURES

Freeze on All New Regulations

On the first day of the new administration, all regulation that had not already been finalized was frozen, via a **Presidential Memorandum**. According to that order, any regulation — including FDA guidance documents and other actions that had not already been finalized — was to be withdrawn and at least a 60-day delay was to be instituted to review the facts, law, and regulatory action and determine whether it could be delayed further or potentially cancelled.

There were two exceptions to this order:

- "Emergency situations or other urgent circumstances relating to health, safety, financial, or national security matters,"
- Situations where there was a legal mandate (either in statute or via a judicial decision) to take a regulatory action by a certain date and the mandated delay would cause those deadlines to be missed.

In addition, the memorandum required that, except for the circumstances outlined above, no new regulatory actions should be taken until approved by a department head appointed by the Trump administration.

While many FDA actions would qualify under the exceptions for health and safety, it is unlikely that many actions related to the advertising and promotion of prescription products would qualify. Consequently, marketers of prescription products should assume no further regulatory actions until, at a minimum, a **new FDA commissioner is approved**.[i]

It is worth noting that while rulemaking activities are covered by this memorandum, FDA enforcement activities such as issuing untitled and warning letters, does not appear to be covered by the freeze.

Repeal Two Existing Regulations for Every New One

Separately, earlier this week, the President signed an additional executive order that mandated that all further regulatory action across the executive branch be neutral in its cost to the regulated industry.

Specifically, the **order mandated** that "the total incremental cost of all new regulations, including repealed regulations, to be finalized this year shall be no greater than zero." To achieve this goal, all agencies are required to evaluate the cost of compliance with any new regulation (which, again, includes not just rulemaking but also the issuance of guidance) and to repeal at least two regulations whose costs of compliance offset the new regulations.

Unlike the Regulatory Freeze Memorandum, there is no exception for the public health regarding the Regulatory Repeal Order. There is, however, an exception if the repeal is "prohibited by law." It's unclear how this Executive Order will be interpreted by the Director of the Office of Management and Budget (Director), who is charged with enforcing it.

Among the issues unique to the Regulatory Repeal Orders application:

- Many actions that the FDA is mandated by law to undertake qualify as regulatory actions subject to this repeal process.

- FDA was just mandated by the passage of the 21st Century Cures Act to issue quite a few guidances, some of which are of interest to marketers.

At a bare minimum, the Regulatory Repeal Order will complicate the process of issuing guidance, regulations and rules. Perhaps the Director will exempt regulatory actions that were required by laws passed prior to the issuance of this Order, since such laws were passed without considering the need to determine which new actions would be exempt from this requirement. That would, though, seem to undermine the overall scope and effectiveness of this Order.

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Former FDA officials and law professors have speculated that some regulations are ripe for repeal. For example, Erika Lietzan, a professor of law at the University of Missouri said in *Regulatory Focus* that "there are probably quite a few regulations on the books that could be removed," including 21 CFR 99, **which seems to be outdated**. In the same piece, former FDA reviewer Erick Turner suggested that the FDA might rescind regulations that permit or require redaction of information that is kept from the public.

It's also worth noting that this Order is explicitly limited to 2017. One possible outcome is that very little new regulation or guidance (except that explicitly required by law) is issued in 2017, and then the pace resumes in 2018.

Among the topics of interest to marketers of prescription products on which FDA has issued draft (but not yet final) guidance, and which are affected by this freeze are the following:

- Use of social media (three draft guidances issued in 2014, with one still pending)
- Electronic submission of promotional materials
- Provision of health care economic information[ii]

- Off-label marketing
- Presentation of risk information (draft guidance issued in 2009 with revised draft on the guidance calendar in 2016 but not 2017)

Freeze on Hiring for FDA and Other Executive Branch Agencies

In addition to the actions directly affecting the Agency's regulatory actions, the new administration also instituted a **hiring freeze** for all executive branch agencies (which includes the FDA). The hiring freeze has a significant impact on the FDA specifically, as it has had several initiatives in place intended to increase the pace of hiring for the Agency. The Office of Generic Drugs alone is in the midst of bringing in 400 new reviewers to speed the approval of new, lower-cost generic drugs.

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The hiring freeze explicitly contains an exemption for the military, and for positions necessary for "national security or public safety." The head of an agency is permitted to make the determination on a case by case basis that hiring meets those exemptions. It's unclear whether all or at least some of the FDA's hiring will meet the public safety exemption.

The FDA receives Congressional appropriations and collects user fees to fund much of its operations and positions. Industry has agreed to these fees precisely to ensure that the FDA is able to hire a sufficient number of qualified people to conduct timely reviews of drug applications, including new drug applications and changes to existing drug approvals. The hiring freeze applies equally to all positions, regardless of "the sources of their operational and programmatic funding."

John Kamp of the Coalition for Healthcare Communication described the impact of the freeze as "especially troublesome" in a communication to membership, because there are currently hundreds of vacancies in the Center for Drug Evaluation and Research.

The hiring freeze is limited to 90 days, and also charges the Director to develop a plan to reduce the number of government employees through attrition.

New FDA Commissioner Yet to Be Named

Finally, although no announcement of an FDA Commissioner nominee has been made, the President did declare during a meeting with industry executives that the nominee has already been determined and **an announcement would happen soon**. In that same meeting, the President declared his intention to speed up the drug-approval process and to reduce the cost, though no details were provided for how these goals will be achieved.

CONCLUSION

As the new administration settles in, there will be additional developments that are likely to impact the marketing of prescription products. Among the most significant developments and areas where people should pay attention are the following:

- Who is named as FDA commissioner?
- How soon is the commissioner named?
- How is the hiring freeze determined to affect the FDA?
- What is the plan for reducing government employees at the FDA, or is the FDA exempted from this plan?
- What steps are taken on drug pricing?

As always, Intouch will be watching for new developments and will continue to keep its clients apprised of relevant information.

Author: Dale Cooke

[i] As of the date of this POV, no one has been nominated to fill the role of FDA Commissioner.
[ii] Note that the 21st Century Cures Act required FDA to issue such guidance, but issuing draft guidance has met this requirement. Finalized guidance is not mandated in the law.