Over-the-Counter (OTC) Monograph Reform Momentum Strong in 2019: Federal Legislation Update in the New 116th Congress

Christine E. Kirk and L. Carter Cornick[1]

Recent developments in Congress deserve the attention of companies with over-the-counter drug products. Major legislation addressing comprehensive reform of the OTC drug monograph process, which nearly passed last year, has been reintroduced and is well on its way toward passage in the current Congress.

The pending reform bill is important for businesses with current OTC monograph products, given the user fee and potential non-patent market exclusivity provisions that are included along with monograph reform in the proposed legislation. Further, the bill may be significant to companies considering entry into the OTC drug market, as well as to companies with products that may inadvertently fall under FDA regulation of OTC drug products due to marketing claims or other reasons (*e.g.*, certain cosmetics and other personal care products with drug-like claims). Additionally, there are provisions specific to sunscreen ingredients. This Bulletin provides a high-level overview of relevant parts of the OTC drug monograph system, a summary of related provisions of the proposed legislation, and AGG observations and considerations for those in the industry.

Background

As noted above, this Bulletin is focused on big picture highlights and does not address OTC drug monographs in detail. We are happy to discuss specific issues and questions on request. As background, some key points about current regulation of OTC drugs include:

- FDA regulates both prescription and nonprescription drugs, including OTC drug products.
- OTC drug monographs establish conditions of use under which an active ingredient or combination of ingredients has been determined to be generally recognized as safe and effective ("GRASE") for use without supervision by a health care provider.
- If an OTC drug product meets the applicable monograph and is GRASE, it is not considered "new" and, thus, does not require FDA prior approval for marketing.[2]

The following items are particularly relevant to the changes proposed in the pending bill:

- Current law requires OTC drug monographs to be proposed and finalized through notice-and-comment rulemaking, which can be extremely time-consuming and resource-intensive. **The reform measure ends the rulemaking requirement. Instead, monographs would be issued by administrative order.**
  - Changes to existing monographs, such as to reflect new scientific or safety information, also require rulemaking. **The reform bill permits changes to be made through the order process.**
- OTC-related work is not currently supported by user fees (*i.e.*, user fees are not required to market these products). **The new bill includes user fee provisions to support OTC drug**

1 L. Carter Cornick, III (Carter Cornick), is the Director of Government Relations and Communications for AGG, and served in the Congress and two Executive departments for 23 years. Mr. Cornick is not an attorney. He has contributed comments such as those regarding the status of the current legislation.

2 We note that OTC monograph drug products are subject to other FDA requirements, such as those related to good manufacturing practices, labeling, and establishment registration and product listing.

work.

- Under current law, there is no pathway for market exclusivity for OTC drug monograph products. **However, the reform measure has provisions that open this door for certain products.**

The decades old OTC drug monograph process has imposed difficult challenges for both FDA and OTC drug company stakeholders. In recent years, FDA, Congress, regulated industry, healthcare providers, and consumer groups have identified areas for OTC process improvement and worked toward reform of the OTC drug regulatory framework. While FDA has made a number of changes using its existing authorities, additional needed changes require legislative action.

Status and Summary of the Proposed Legislation

Current Status of H.R. 269

As the 115th Congress drew to a close last year, OTC monograph reform legislation was nearly enacted.[3] Bipartisan House and Senate support was strong enough and broad enough that the OTC bill was a candidate for final passage to be sent to the President for approval. However, typical "end of session" action to move measures like the OTC reform bill – *e.g.*, as a rider to another bill – was derailed as Congress and the White House deadlocked on critical appropriations legislation that carried hotly debated provisions related to the U.S. southwestern border, resulting in the partial federal government shutdown that ended last month.

In the first 4 weeks of the new Congress, the bipartisan (House and Senate) support for OTC reform carried forward into 2019. By January 8th, the House passed, overwhelmingly, H.R. 269 (the "Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019"), **adding OTC reform titles to the bill** (the "Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019," approved, 401 – 17). Two days later, the Senate leadership advanced the Pandemic legislation – containing the OTC reform provisions – making H.R. 269 available for full Senate approval. Since the House-passed measure reintroduced the provisions fully agreed to by both chambers weeks earlier, Senate leadership determined that there is no need for a separate Senate bill or additional review by Senate committees or subcommittees.

While it is too early to say when the Senate may approve OTC Monograph Reform, - it is noteworthy that passage is possible sooner than would normally be expected (bearing in mind that there are no guarantees relative to when the Senate will act). Once the President receives legislation approved by Congress, it becomes law within 10 days (unless it is returned to the Congress with objections).

Key OTC Reform Provisions of H.R. 269

Note: OTC monograph reform is part of a larger bill addressing pandemic preparedness (H.R. 269). While those provisions are outside the scope of this Bulletin, readers engaged in work related to medical countermeasures and pandemic preparedness (e.g., developing certain antibiotics and vaccinations; preparing health facilities and providers to handle epidemic diseases) will be interested in the pandemic preparedness provisions of H.R. 269.

The pending OTC monograph reform legislation includes provisions that would make significant changes to the current drug monograph system. Among other provisions, major reforms include:

- **Monographs issued by order, rather than rulemaking**
  - The bill authorizes the Secretary of HHS to issue an administrative order to propose, finalize, or change an OTC drug monograph.
  - The administrative order process is generally faster than notice-and-comment rulemaking. This is expected to make the OTC monograph process more efficient.
  - The bill provides for transparency, fairness, accountability, and appeal rights – including public notice, hearings, and judicial review – related to the administrative order process.

3 *See* "Over-the-Counter Drug Safety, Innovation, and Reform Act of 2018" (H.R. 5333; S.2315).

- **User fees**
  - The bill would establish a user fee program for OTC drug products.
  - Fees would include facility fees and fees for certain monograph requests (*e.g.*, requests that the agency issue a new drug monograph order or change the contents of an existing monograph).
  - Fees would support review of monograph requests, inspection of OTC facilities, and other OTC drug-related activities.

- **Provisions addressing the status of currently marketed OTC drug products**
  - The bill addresses what would happen to currently marketed OTC drug products upon enactment of the OTC monograph reform legislation.
  - The result for each product would depend on the existing monograph status (final, tentative final, proposed, or advanced notice of proposed rulemaking) and on the GRASE category of the OTC active ingredient or combination of ingredients (Category I-GRASE, Category II-not GRASE, or Category III-more data needed).
    - Currently marketed OTC drugs that are in compliance with a final monograph, and those that are classified in Category I under a tentative final monograph, would generally continue to be considered GRASE and not be considered "new" drugs, so long as they meet other applicable requirements (e.g., general requirements for non-prescription drugs).
    - There are specific provisions regarding treatment of OTC sunscreen drugs.

- **Limited exclusivity for certain OTC drug products**
  - The bill would authorize market exclusivity for up to 18 months for qualifying OTC drug products that:
    - contain an active ingredient (including any ester or salt of the active ingredient) not previously incorporated in a monograph; or
    - provide for a change in the conditions of use of a drug, for which new human data studies conducted or sponsored by the requestor (or for which the requestor has an exclusive right of reference) were essential to the issuance of the monograph order; and
    - meet other applicable requirements.

- **Provisions related to sunscreen ingredients**
  - The bill addresses the current sunscreen monograph and the interaction of orders issued under the Sunscreen Innovation Act of 2014 (Pub. L. 113-95) ("SIA") with the provisions of the OTC monograph reform legislation.
    - Sponsors that have received SIA-related proposed orders regarding sunscreen ingredients that were previously proposed as GRASE for OTC use would have 180 days from enactment of the new legislation to determine whether to continue within the SIA framework or transition to the new OTC monograph process.

- **General regulations continue to apply**
  - Except as specifically provided, the bill does not supersede regulations establishing general requirements for nonprescription drugs, such as labeling requirements in CFR Part 201.

AGG Observations

- Passage of OTC drug monograph reform legislation could occur at any time. While approval is not guaranteed, the bill could be brought up for a vote at any time that the Senate leadership determines is appropriate.
  - Now is a good time for companies with OTC drug products to consider how the proposed legislation may affect them. Among other things, companies should confirm which type of monograph covers each of their OTC drug products (final monograph, tentative final monograph, proposed monograph, advanced notice of proposed rulemaking) and which category applies to the OTC active ingredient(s) or combination of ingredients (*i.e.*, I-GRASE, II-not GRASE, or III-more data needed). This is relevant to

the status of the product under the new process.
    - Companies with sunscreen products may want to review the provisions of the bill regarding the existing tentative final monograph for sunscreens. In addition, they may want to consider the interaction of the SIA and OTC monograph reform provisions, particularly if the company is a sponsor of, or otherwise interested in, sunscreen ingredients that are the subject of orders issued under the SIA framework.

- While certain provisions of the OTC monograph reform legislation are relatively clear (*e.g.*, if the proposed bill is enacted, there will be user fees for OTC drugs), the details of implementation and the potential downstream effects of OTC monograph reform remain to be seen. For example:
    - How (and how soon) will FDA transition from the current drug monograph rulemaking process to the proposed order process?
    - What will happen with regard to currently-marketed OTC products that may have a status change under the OTC monograph reform legislation? Will FDA provide an additional compliance period or exercise enforcement discretion?
    - What are the details of the proposed exclusivity provisions? How might current and future OTC drug products be affected?
    - When and how will the proposed user fee program be implemented?

- There are other recent developments of note in the OTC drug area. For example, in 2018, FDA issued a number of warning letters and took other enforcement actions related to good manufacturing practices for OTC products. In 2018, FDA also issued draft guidance on innovation for OTC products as well as draft guidance on maximal usage trial ("MUsT") product absorption studies in the OTC context.[4]
    - Companies with OTC drug products may want to take this opportunity to update or refresh their understanding of the existing OTC regulatory landscape and to confirm that their policies and practices are in compliance with current requirements.

4 FDA, Draft Guidance for Industry, *Innovative Approaches for Nonprescription Drug Products* (July 2018), available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM613666.pdf, and FDA, Draft Guidance for Industry, *Maximal Usage Trials for Topical Active Ingredients Being Considered for Inclusion in an Over-The-Counter Monograph: Study Elements and Considerations* (May 2018), available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ UCM608356.pdf.

Authors and Contributors

Christine E. Kirk
Associate, DC Office
202.677.4936
christine.kirk@agg.com

L. Carter Cornick
Director of Government Relations and Communications, DC Office
202.677.4036
carter.cornick@agg.com

not *if*, but *how*.®

About Arnall Golden Gregory LLP

Arnall Golden Gregory (AGG), an Am Law 200 law firm with 167 attorneys in Atlanta and Washington, DC, takes a "business sensibility" approach when advising clients. AGG provides industry knowledge, attention to detail, transparency and value to help businesses and individuals achieve their definition of success. AGG's transaction, litigation, regulatory and privacy counselors serve clients in healthcare, real estate, litigation matters, business transactions, fintech, global commerce, government investigations and logistics and transportation. AGG subscribes to the belief "not if, but how."
Visit us at www.agg.com.

Atlanta Office
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Avenue, NW
Suite 1000
Washington, DC 20006

To subscribe to future alerts, insights and newsletters: **http://www.agg.com/subscribe/**