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Outlook for OTC drug regulation

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On the horizon

Significant change is on the horizon for the OTC drug industry. OTC drug sales have grown from about US$3 billion in 1972 to over US$34 billion today, with over 300,000 products marketed. Through a combination of new legislation, regulations, and enforcement policies, a new regulatory framework is coming for OTC drugs. Companies will want to prepare for the new opportunities and challenges that will arise. Anticipating and planning for these legal and regulatory changes and their impact on the business environment will be essential to obtaining (or maintaining) a competitive advantage.

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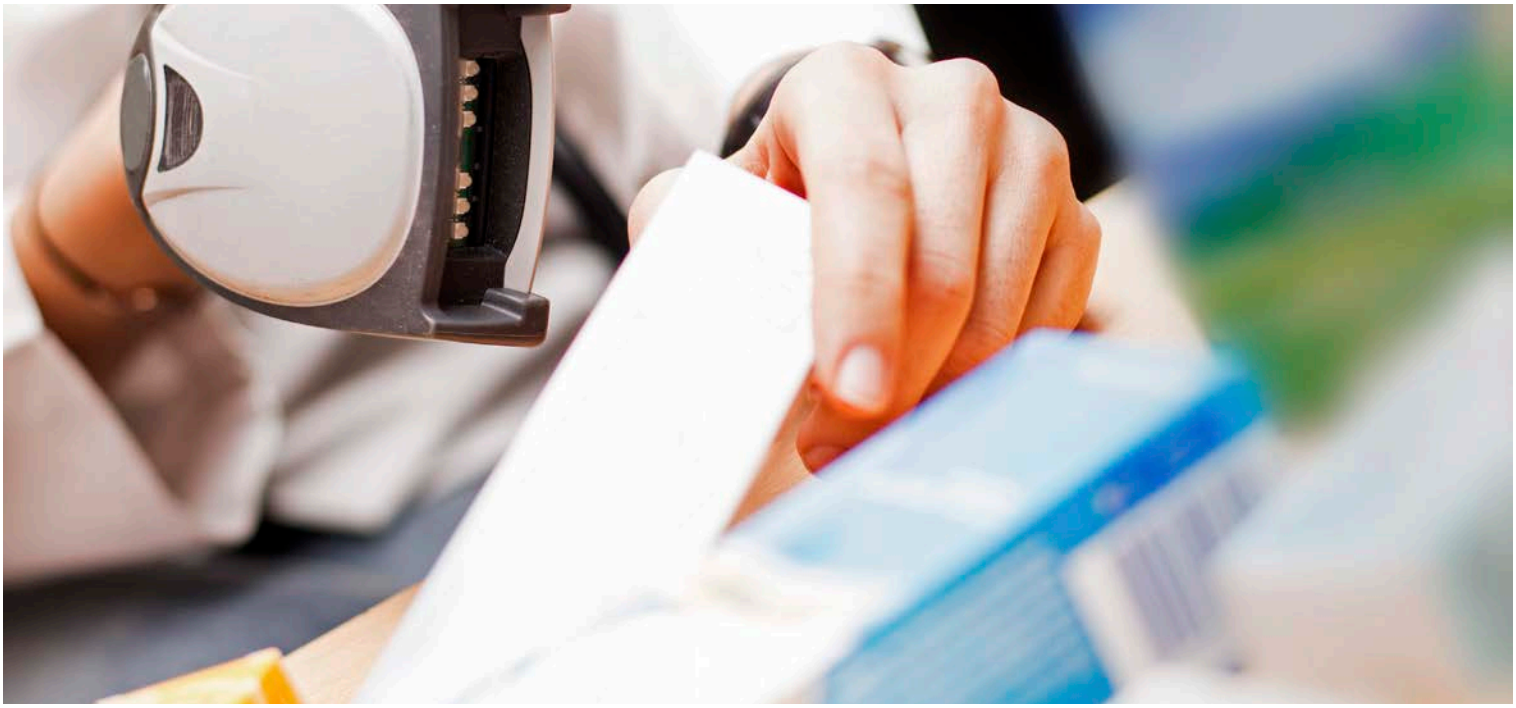

Legislation will fundamentally change OTC drug regulation

Legislation is pending in Congress that would significantly change how OTC drugs are regulated. The legislation appears to have the strong support of FDA and industry, as well as bipartisan support in both houses of Congress, and we expect it to pass in 2018.

What's going to change?

- **Modernization**. The current OTC drug monograph system is slow and antiquated. As a practical matter, the monograph system is limited to drugs that were marketed in the U.S. in 1972. Changing requirements and labeling to account for new science on effectiveness and safety for these drugs has been painfully slow, as demonstrated by the fact that about one-third of the monographs remain incomplete after 46 years.
- **User fee program transformation**. The legislation includes a user fee program, with rigorous performance goals, that will provide FDA with substantial new funding to revamp the regulatory oversight of OTC drugs. It will reform the monograph system by expediting agency action to accommodate product innovation and evolving science and better enable the agency to respond to urgent safety issues.

Opportunities

- **New ingredients and dosage forms**. New drugs will be permitted for OTC use that were not marketed in the U.S. before 1972. Innovative dosage forms that are more palatable, convenient, and appealing to consumers will be authorized for marketing.
- **Possible exclusivity**. In certain cases, it will be possible to obtain a period of exclusivity (possibly 18 months) if a clinical study was essential to obtaining marketing authorization for a new OTC drug product.
- **Clarity and predictability**. FDA's regulatory paralysis for OTC drugs will end, requiring the agency to act promptly and within predictable timeframes to review applications for marketing authorization for new OTC drug products.

Challenges

- **New competition**. The approval of new OTC drugs and dosage forms, including possible exclusivity for some, will shake up the OTC drug marketplace with new competitors.
- **User fees**. There will be an application fee of up to US$500,000 for obtaining FDA review of a data submission for a new OTC drug marketing authorization, and each facility at which OTC drugs are manufactured will be subject to an annual fee, the cost of which has not yet been determined.
- **New packaging requirements**. FDA will have enhanced authority to require new packaging for OTC drugs, including unit dose packaging, which could be more costly than current packaging and container closure systems.
- **Market withdrawals**. Because FDA will have additional resources and will be seeking to expedite regulatory action, products that FDA has determined to be non-monograph under the current system may need to be reformulated or come off the market. And FDA action that had been stalled may proceed, resulting in decisions that require additional reformulations or market withdrawals.
- **Possible increases in regulatory scrutiny**. With the additional user fee resources, FDA may expand its inspections of OTC drugs, including more intense or frequent scrutiny of manufacturing quality. The agency may also pay closer attention to the inactive ingredients in OTC drug products, more akin to how FDA regulates prescription drug inactive ingredients.

Regulations will expand the universe of OTC drugs

In December 2017, FDA announced its intention to initiate rulemaking to allow certain drugs that currently require a prescription to be made available as OTC drugs.

What's going to change?

- **OTC with conditions**. These drugs would be sold without a prescription but only under conditions designed to provide assurance that consumers could safely self-select and use these drugs without a prescription.
- **New technologies**. For example, technologies that could provide conditions for safe self-selection might include mobile medical apps and retail pharmacy kiosks that provide diagnostic or other screening services.
- **Increased access to care**. By providing easier access to certain drugs, the new regulations could help address the under-treatment of certain diseases and provide consumers with greater opportunities to become more directly engaged in their health care.
- **Possible expanded role for pharmacists**. This new paradigm might lead to certain drugs kept behind the pharmacy counter and dispensed under certain conditions, such as pharmacist consultation. This could include, for example, refills of certain prescriptions without prescriber intervention.
- **Moving forward**. FDA has considered making this shift since at least 2012, when the proposal was known as the Non-Prescription Safe Use Regulatory Expansion (NSURE). This is the first time FDA has announced its plans to actually initiate rulemaking to implement the program.
- **Possible legislative component**. Although rulemaking is generally a very slow and cumbersome process, Congress could accelerate the implementation of this program by using the OTC monograph reform legislation to clarify and expand FDA's authority in this area.

Opportunities

- **Rx to OTC switches**. If regulations are finalized or legislation is enacted for this program, it will significantly increase the number and variety of drugs that can marketed without a prescription. For many products, this would be expected to lead to substantial increases in sales volume.
- I**nteraction with OTC drug monograph reform**. If monograph reform is enacted, it could provide a streamlined and predictable pathway for obtaining administrative orders that will for the first time allow categories of products to become available without a prescription.

Challenges

- **New competition**. The entry of new drug products in the OTC space may erode market share for existing OTC products, many of which have been marketed for many years with limited competition.

Greater requirements for homeopathic drugs

Sales of homeopathic drugs have grown markedly, almost doubling over a ten year period, and exceeding US$1 billion in recent years. The sales are usually as OTC drugs, but without the kind of scientific evidence that FDA and FTC expect for other drug products.

What's going to change?

- **New enforcement policies**. In 2016, FTC announced a stricter enforcement policy for homeopathic drugs that will require promotional materials to include strong disclaimers for health claims that cannot be adequately substantiated with scientific evidence. In 2017, FDA issued draft guidance identifying categories of homeopathic drugs that will be subject to enforcement, based on potential risks to consumers. How and when these policies are implemented remains to be seen.

Opportunities

- **Competitor market share**. Where homeopathic drugs compete with OTC drugs, it is possible that implementation of the new policies could create opportunities for certain non-homeopathic competitors to increase market share.

Challenges

- **Increased regulatory risk**. Going forward, there may be an increased risk of FTC regulatory action against certain homeopathic drugs. FDA may also adjust its enforcement in this area, but the impact would affect a narrower range of products.
- **Additional constraints**. Manufacturers of homeopathic drugs may be more constrained in introducing new products with health claims lacking scientific substantiation. And complying with FTC-required disclaimers, as well as increased FDA scrutiny for certain homeopathic products, may adversely affect sales for certain homeopathic drugs.

Legislation to strengthen cosmetic regulation

Congress is also considering legislation to strengthen FDA's regulatory authority over cosmetic products. At present, FDA's occasional enforcement actions against cosmetics are often about marketing claims crossing the jurisdictional line between cosmetics and drugs, such as claims to treat a disease/condition or affect the structure or function of the body. Although this legislation (unlike OTC monograph reform) has an unclear future, it could give FDA user fee resources to oversee cosmetics, which might lead to greater enforcement activity, and of a broader scope, including labeling, manufacturing quality, ingredient/product safety, and promotional claims. This may be an opportunity for manufacturers or distributors of competing OTC drugs, as well as those cosmetic companies prepared to operate in a more stringent regulatory environment.

Anticipating and preparing to seize opportunities and manage risks

Building on decades of experience in FDA and HHS, Hogan Lovells attorneys are steeped in the regulatory issues applicable to OTC and homeopathic drugs. Our experience allows us to help clients successfully conduct their businesses in this highly-regulated environment by identifying opportunities and risks, and developing and implementing creative and practical actions.

Our assistance can include:

- Integrated advocacy, drawing upon extensive legislative and regulatory experience, in order to:
  - Contribute to the substance of monograph reform legislation.
  - Shape implementation of monograph reform legislation, such as by guidance documents or administrative orders.
  - Participate in development of new regulations that will expand the universe of drugs available OTC with new conditions and requirements.
- Strategic and regulatory counseling to:
  - Address the new regulatory and competitive landscape.
  - Provide real-time analysis of potential changes to the regulatory framework to inform business decision making.
  - Prepare for and respond to the heightened FDA inspectional oversight for manufacturing quality (CGMP) that increased resources from user fees will fund.
- Practical advice based on experience with the current regulatory framework, including with regard to:
  - Marketing products under the current OTC Monograph system, focusing on ingredients, conditions of use, labeling, and enforcement policies.
  - Obtaining approval of NDAs for OTC products.
  - Rx to OTC switches.
  - Marketing homeopathic OTC drugs.

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Heidi Forster Gertner

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Heidi Gertner works at the forefront of the drug regulatory industry. She provides insight to large and small pharmaceutical companies and research institutions in dealing with government regulators to maximize business potential.

With her wealth of drug regulatory knowledge and creative thinking skills, Heidi finds solutions to client problems and is a tireless advocate. She helps clients resolve their enforcement differences with the FDA and facilitates positive relationships with the agency. Heidi anticipates and helps clients dealing with cutting-edge issues, both by assessing policy initiatives and finding new business opportunities.

Heidi began her professional career with a focus on bioethics and law, completing two post-doctoral bioethics fellowships, one at the Cleveland Clinic Foundation, and another at the National Institutes of Health. At the National Institutes of Health Heidi's work focused primarily on human subject protection and research ethics issues.

Heidi honed her legal skills at the FDA's Office of Chief Counsel, where she advised government regulators on almost all aspects of drug regulation for 13 years. At the FDA, Heidi's portfolio focused on drug advertising and promotion, combination products, drug safety, clinical trials and human subject protection, Rx-OTC switches, and over-the-counter drug regulation. While at the agency, she oversaw numerous rulemaking and enforcement actions. As one of a handful of senior lawyers, Heidi worked closely with the Center for Drugs, HHS officials, and congressional staff.

Heidi joined Hogan Lovells in 2014 and calls the D.C. office her home base. She is plugged into the D.C. regulatory scene and works closely with companies and research institutions on developing regulatory and business strategy. She is an integral part of the skilled team of drug regulatory lawyers and works across numerous groups within the firm to provide clients with comprehensive legal and business advice. She is also an adjunct professor of law at American University's Washington College of Law, where she has challenged students in her Health Law Bioethics class for the past 15 years.

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Services

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Marketing and Advertising

Pharmaceutical and Biotechnology Regulatory

Education

J.D., Washington University in St. Louis School of Law, 1997

B.A., cum laude, Binghamton University, 1994

Awards and Rankings

HHS Secretary's Award for Distinguished Service

FDA Outstanding Service Award

Commissioner's Special Recognition Award, *FDA Commissioner's Award of Excellence*

David Horowitz

Partner, Washington, D.C.

David Horowitz brings 25 years of combined experience at the U.S. Department of Health and Human Services (HHS) and the FDA to help clients anticipate and navigate regulatory challenges, and participating in the policy-making process.

As Deputy General Counsel at HHS (2010-2017), David oversaw and coordinated legal services in support of FDA, the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and international and emergency preparedness programs. His work focused on FDA regulatory policy and litigation. During his tenure at FDA — which included five years as head of the Office of Compliance for drugs, and three years as Assistant Commissioner for Compliance Policy — David played a leadership role in major initiatives, including the modernization of FDA's approach to pharmaceutical manufacturing quality and the agency's efforts to develop and implement a more scientific, risk-based approach to inspection and enforcement.

Over the course of his career at HHS and FDA, David developed substantial knowledge pertaining to FDA law and policy, with particular emphasis on pharmaceuticals, compliance, and the application of administrative law. He also developed a deep understanding of the institutions, organizational structures, procedures, and cultures through which regulatory policy and compliance decisions are considered, developed, and implemented across all branches of government, including Congress and the courts, as well as various components of FDA, HHS, Office of Management and Budget, Department of Justice, and the White House.

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Government Relations and Policy Advocacy

Pharmaceutical and Biotechnology Regulatory

Education

J.D., University of Virginia School of Law, 1991

B.A., magna cum laude, Brown University, 1986

Awards and Rankings

FDA Award of Merit, *FDA*, 1999, 2007

HHS Certificate of Appreciation, *HHS*, 2010, 2015

NIH Director's Award, *NIH*, 2011

Distinguished Service and Leadership Award, *Food and Drug Law Institute*, 2015

FDA Commissioner's Special Citation, *FDA*, 1994, 1998, 2005, 2006, 2015

Meritorious Service, *Presidential Rank Award*, 2016

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Whether you're a global pharmaceuticals company or a biotechnology startup, accomplishing business goals in such a highly regulated industry requires practical, integrated legal analysis and advice.

We are creative in solving your problems thanks to our background and experience. We not only know the law, we know the nuances of the law because many of our lawyers have worked in the U.S. Food and Drug Administration. Others have worked in industry, which means we also understand your business, the science behind your business, and your marketplace. And to provide integrated advice across jurisdictions, our pharma/biotech lawyers in Europe, Asia, and Latin America collaborate closely with our U.S. team, which is the largest in the nation dedicated to providing regulatory legal services to the industry.

Our services are as varied as the challenges you face. We offer timely, effective counsel on matters that include product development, approval, post-approval compliance, and the development of next-generation products. Our lawyers concentrate on particular areas of the law, such as advertising, manufacturing compliance, regulatory exclusivities, and controlled substances. And when your issues overlap with other disciplines, such as intellectual property, litigation, or healthcare compliance, we reach across the firm to tap into the needed expertise, especially in our strong health practice.

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- Lifecycle management
- OTC drugs
- Regulatory exclusivities
- REMS / drug safety
- State regulation

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Our team has advised 22 of the top 25 pharmaceutical and 9 of the top 10 biotechnology companies in the world, in the last year.

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We take the time to learn the nuances of your business, and build these into our strategic approach. We also understand the political and policy-making environment in which you are engaged to make sure that we are respected and trusted by legislators and policy makers.

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Navigating complexities in the life sciences and health care industries is no easy task. Successfully competing in the space requires increasingly creative strategies and integrated solutions that protect and support your business day in and day out.

Regardless of the sector of the health care industry in which you operate or the maturity of your products, we understand how to bridge the gap between the challenges you face and the outcome you want. From budding startups to multinational enterprises, we've been there before and know how to position you for success.

With more than 500 life sciences and health care lawyers across the globe, we work closely with you and each other to tackle tough issues and difficult-toenter markets – no matter where you are today or want to be tomorrow. And because we know what makes your industry tick, we have a deep understanding of the issues you face – helping you stay ahead of the curve and on top of your opportunities.

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- Commercialization

Markets we serve

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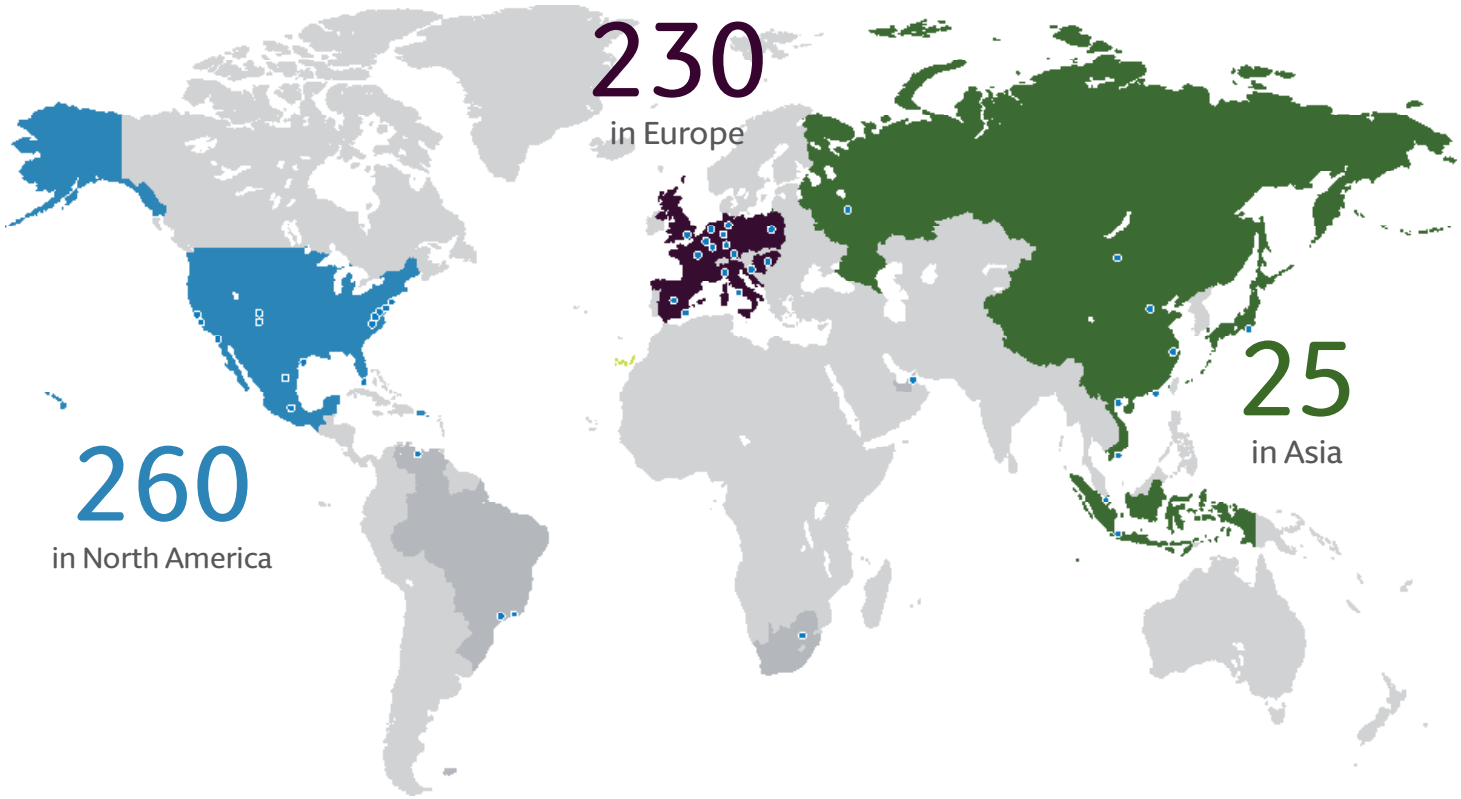
Over 500 life sciences and health care practitioners worldwide



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