The Crowell & Moring
Product Risk Management Group

CRISIS MANAGEMENT HANDBOOK

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TABLE OF CONTENTS

DISCLAIMER

FOREWORD

When Your Brand is at Stake: Developing a Comprehensive, Lasting Approach to Product Risk Management

Worrying about a possible business crisis to a marquee product line or innovation can certainly keep any executive or in-house counsel up at night. Being in the middle of an actual crisis is even more of a nightmare. Whether it be an alleged safety issue, problems with your supply chain, false and misleading competitive advertising claims, seizures at the border, regulatory agency investigations, or full-fledged litigation (just to name a few), product- and brand-related crises can have devastating effects on the bottom line and your company's goodwill with customers and shareholders. Dealing with these crises also creates major disruptions to your business. The good news is that proactive measures do exist that can position your business to reduce the chances that crises hit, and be ready to act swiftly and effectively to minimize negative fallout when crises are unavoidable.

We intend this handbook to be a guide and an essential reference before you launch a new product line or other innovation – to help you identify potential legal risks throughout the product's anticipated lifecycle and use the tools discussed to minimize, where possible, these potential risks. We also encourage you to consult this book for product lines and innovations already in production, because it is never too late to implement risk avoidance and mitigation tactics. Building risk management into the lifecycle of your innovations, from design and testing through marketing and distribution, are addressed throughout the ensuing chapters. Key issues that arise along the way such as document creation and product stewardship policies are also covered.

In addition, should you find yourself in the middle of a full-fledged legal crisis involving your product, brand, or innovation, this handbook provides quick resources to assist in identifying issues and considerations key to an effective and appropriate response. Of course, there is no "one-size fits all" approach to legal risk management. Every business and every product or service presents its own unique issues. But the hypotheticals and general principles discussed in this book can help businesses think creatively about ways to minimize – or, better yet, avoid – potential negative impacts.

The purpose of any legal risk management strategy is to help the business grow and achieve its goals with minimal obstacles. Businesses that integrate legal risk management throughout the full lifecycle of their innovations are often best prepared to thrive in any storm. Crowell & Moring's Product Risk Management Group approaches legal risk management from a multi-disciplinary and product life cycle approach, bringing expertise from inside regulatory agencies, the Hill, and the courtroom. Should you have any questions about developing a comprehensive legal risk management strategy for your company, or about any of the issues addressed in this handbook, please feel free to contact the attorneys listed at the back of this handbook for more information.

CHAPTER 1

Innovation Done Well: Designing Away Risk

Be Proactive In Designing Away Legal Risks

Identifying and addressing legal risks proactively at the product design stage can mitigate, or even eliminate, future legal risk, including reducing potential exposure to costly class action litigation. For example, design defect claims feature prominently in product liability lawsuits, with a plaintiff (or class of plaintiffs) claiming that the design of a product is inherently defective or dangerous, rendering every unit of the product defective. Failure to warn claims are also common, alleging that the inherent risk of a design could have been mitigated with proper warnings, but that the manufacturer failed to include such warnings on the product. Because all units of a mass-produced product typically share the same design and bear the same warnings, these claims have the potential to generate costly and burdensome class action lawsuits. Companies can mitigate these legal risks from the outset by proactively identifying and designing away potential risks, and working with experts, including an attorney, experienced in balancing business goals, consumer demands, and a company's legal risk tolerance, while ensuring compliance with the myriad state and federal applicable laws and regulations.

In designing away risk, it's not always necessary to assume that the worst-case scenario will arise. The goal is to be practical, but informed and aware of potential legal landmines. In some cases, it may be possible to identify alternatives to full-blown risk assessment that can keep costs down and speed the innovation process for a new product. For example, similar products often have similar risk profiles, and compliance with

industry standards may serve as whole or partial surrogates in some cases for independent risk assessment.

There are a number of components and considerations to a design risk assessment, including:

- Compliance with applicable industry standards, laws and regulations;
- Inherent risks and dangers in the design and obviousness of those risks and dangers;
- Warnings/education to mitigate inherent risks and dangers;
- Availability/feasibility of safer alternative designs;
- Safeguards or other product enhancements to prevent risk; and
- Litigation profile for similar products and risks.

Of course, not all risks can, or need to, be mitigated. Identify, gather, evaluate, and synthesize the relevant information, being mindful about document creation that reflects safety-conscious and defensible decision-making. Consider consulting with technical, scientific, legal, or medical specialists concerning safer design alternatives where appropriate.

Sometimes risks are inherent to the product, cannot be eliminated, and no safeguard is technologically feasible. At that point, a hazard assessment should guide consideration of whether warnings will suffice to reduce potential legal risks within the company's level of tolerance. An assessment of the potential frequency and severity of possible injuries aids in prioritizing warnings. Evaluate whether proposed warnings, labeling, and advertising comply with state and federal laws, whether they effectively communicate risks of use and reasonably foreseeable misuse, and whether they must comply with or be guided by industry standards or government guidelines. The assessment may also include

other considerations affecting comprehension, such as whether the label should include pictures, whether warnings should be in more than one language, and the placement of labels and warnings on the product and packaging. Focus groups of users or consumers can help inform decision-making on warning issues and aid in prioritizing the priority and placement of warnings.

Design Products With Potential Regulatory Regimes In Mind

A product's design may influence whether and to what extent it is regulated by a local, state, federal, or international agency. For example, a product may be deemed a "children's product" based on certain design features, subjecting it to heightened regulatory standards and a heightened risk profile, even though the manufacturer did not intend the product primarily for children. Expanding into new product areas may warrant consulting with experts experienced in counseling manufacturers and retailers on regulatory compliance to help to avoid unintentional (and unwanted) product regulation.

In addition to the design itself, the materials from which a product is made should be chosen carefully, as they may increase or decrease the level of legal risk associated with the product. For example, California has many state-specific requirements concerning the chemicals contained in products sold in the state. Proposition 65 requires the state to publish a list of chemicals known to cause cancer or birth defects or other reproductive harm. This list has grown to approximately 800 chemicals. Companies doing business in the state of California have a duty to provide "clear and reasonable" warnings before knowingly and intentionally exposing anyone to a listed chemical. Any product which could ultimately end up in the state of California is subject to Proposition 65 requirements, even if they are not directly sold in the state. Warnings

can be given in a variety of different ways, including product labeling, or posting signs. Penalties for violating Proposition 65 by failing to provide notices can be as high as $2500 per violation per day, so compliance is critical.

California has also proposed Safer Consumer Products Regulations, which are among the first comprehensive, state-level efforts to find safer alternatives to hazardous chemicals and viewed by some as a possible national model for chemical reform. If finalized, the regulations will impose obligations on manufacturers, importers, and retailers of consumer goods if their product contains chemicals designated as Chemicals of Concern within Priority Products. Companies may be required to prepare an alternative analysis to determine how to limit potential exposures and focus on identifying safer alternatives. Under the regulations, the State may restrict the use of chemicals, prohibit sales of products, or impose engineering or administrative controls on the company's use of the chemicals. Awareness and consideration of the potential for these types of state obligations early in the design process may help to avoid expensive alternative analysis down the road, especially if substitute components can be incorporated. Michigan was the first state to establish a policy encouraging the use of safer, less toxic, chemical alternatives. In addition, to date, Washington, Connecticut, Maine, and Minnesota have already enacted "green chemistry" legislation, some of which are specifically targeted at promoting safer children's products. Other states, including Illinois, Massachusetts, New York, Oregon, and Vermont, are in the process of pursuing similar legislation.

Post-Design Effective Product Stewardship

Pre-launch design risk management doesn't end once the design and materials are finalized. Product stewardship includes conducting product

safety and compliance testing, and documenting those efforts as well as monitoring customer complaints and effectiveness of warnings and instructions. Some jurisdictions have imposed an independent "duty to test" in product liability cases, and manufacturers have been held liable where courts have found that defects would have been discovered with reasonable testing. At a minimum, test products to the applicable standards. Good practice, however, may dictate going beyond the standards, such as by simulating foreseeable use and misuse, testing to failure, or simulating a full product lifecycle to evaluate the effect of environmental factors. In addition, monitoring consumer returns or complaints can provide early warning signs of potential issues.

Establish and follow appropriate and legally required documentation and record retention pertaining to design, manufacturing, and product stewardship. Maintaining batch and lot records can help limit the scope of a recall in the event of an unanticipated manufacturing defect or chemical contamination of a product. Documenting the risk assessment process is important, as it captures the company's thinking as to potential problems, and provides evidence of the company's commitment to minimizing and preventing risks and to designing and creating safe products.

Robust risk management that begins at the design stage cannot guarantee a risk-free product. It can, however, reduce exposure to regulatory sanctions and product liability lawsuits, as well as create a more defensible product and a more defensible corporate commitment to product safety, in the event problems do arise.

CHAPTER 2

How Internal Policies and Practices Can Prevent or Fuel a Crisis: Developing an Effective Corporate Crisis Plan

Your company learns that its only product has been reportedly involved in several deaths across the country. Regulatory authorities are aware of the incidents, and plaintiffs' attorneys are in contact with your company's counsel. The press is calling corporate headquarters seeking information and requesting a statement. How does your company respond?

This scenario has occurred numerous times in the past. Developing a corporate crisis response plan in advance gives your company a better chance at successfully weathering a crisis. These events arise quickly, frequently require a lot of manpower to manage, may significantly drain your company's resources, and could have long-term effects on the business if not handled properly. Your company should understand the risks inherent in its business and develop a workable response plan.

Listed below are some of the critical pieces of a crisis response plan:

Crisis Team. A cross functional crisis team should be assembled, and team members assigned roles. Clear lines of decision making authority for the duration of the crisis should be established. The team should brainstorm the scope of the crisis and anticipate all that could go wrong as the crisis unfolds.

Internal Investigation and Remediation. One of the first steps your company should take in the face of a crisis is to determine the root cause of the problem and develop a plan to fix it. The

investigation may be handled internally, by an outside firm, or by a combination of the two. In addition, involving outside counsel early in the crisis will make it more likely that the investigative work and analysis will be covered by privilege and protected from disclosure to a third party in the future.

At the outset, your company should consider whether it should stop sale, shipment, or even manufacturing of the product at issue during the investigation. Communicating that message through the supply and distribution chain may be a complicated and sensitive process that should be planned before a crisis hits.

Once the root cause has been determined, your company may need to determine how to fix the problem and implement controls to prevent it from happening again. At this stage, it may be necessary to involve external experts and, in some cases, regulatory authorities. Counsel should also be closely involved at this stage to strategize how these decisions affect legal liabilities.

Public Relations. The media often aggressively pursues stories about product safety crises and may publicize and shape public opinion about a crisis early on, even before a company fully understands what has happened. In most cases, a company in the midst of a crisis should talk to the press based on a carefully crafted plan.

External public relations consultants may be hired to take the lead on press inquiries, and the work of those consultants may be privileged if hired by outside counsel. It is important to understand that any statement provided to the media may later dictate the company's position in the face of a government

enforcement action or civil litigation. Your company should thus carefully develop the theme of its responses at the earliest stages and ensure it provides consistent messaging.

Regulatory Notice. Federal regulatory agencies, such as the Consumer Product Safety Commission, National Highway Traffic Safety Administration, Food and Drug Administration, or state Attorneys General, for example, may be involved during a product safety crisis, particularly when a recall or other corrective action is required. Thus, it is important to understand the laws and regulations applicable to your company's products and operations and whether it has any obligation to report incidents to any government agencies long before a crisis takes place. This plan may include designating employees who are in charge of compliance obligations, as well as consultation with outside counsel. If the product has been sold internationally, those reporting obligations must be considered as well.

Corporations should also be aware of potential enforcement actions and penalties that may result from a crisis. Corporate officers and employees may be exposed to civil and criminal liabilities for their involvement in the underlying crisis. Your company may benefit from consulting with legal counsel when navigating these communications with the government.

Litigation. The company might not be sued until after it has dealt with its investigation, remediation, public relations, and regulatory pressures, but early actions may dictate litigation strategy. Your company may be forced to develop and stick to its trial themes from the outset. It may also be of benefit to have legal counsel forecast the nature of any potential litigation that may develop

as a result of the crisis, identify possible defenses, and project exposure to damages. That could be critical information for a business in evaluating its tolerance for risk in navigating a crisis.

Your company cannot predict when or where a crisis may hit or fully prevent negative legal or reputational fallout. However, thinking through critical issues, taking the time to develop a response plan before a crisis occurs, and being ready to respond will increase your company's chances of successfully weathering the storm.

CHAPTER 3

Managing Documents Created Before, During, and After a Product Liability Crisis

Creating the Right Documents During the Product Life Cycle and Preserving Them in the Ordinary Course of Business

Take care not to draft "problematic" documents: assume every document you create will be used against you in litigation, will be an exhibit at trial, or quoted in the press. Some additional thoughts to consider include:

- Avoid sarcasm, humor, contempt, or expletives.
- Don't speculate, offer unsupported opinions, or misrepresent facts.
- Don't express legal opinions if you're not a lawyer.
- Don't create or send unnecessary documents.
- Don't exaggerate.

Take steps to maintain legal privileges and protections over documents. Possible steps include:

- Use outside counsel to attach and protect legal privilege over testing and studies.
- Involve counsel in communications with experts.
- Know and operate within parameters of local privilege rules.

Preserving Your Documents in the Ordinary Course of Business

Create and implement a comprehensive document retention policy that

is uniform and uniformly followed. Key considerations include:

- Essential documents should be retained as long as reasonably necessary.
- Non-essential documents should be automatically purged at regular intervals.

Retain all documents for the length of time required by law or regulation. Keep in mind the following:

- Various laws and regulations include record retention requirements for certain materials. *See, e.g.*, 49 C.F.R. § 576.5(a) ("[e]ach manufacturer of motor vehicles, child restraint systems, and tires shall retain [specified records] for a period of five calendar years").
- When multiple legal record retention requirements may apply, retain documents for the longest required time period. *Compare, e.g.*, Consumer Product Safety Commission document retention rule for manufacturers and importers of cribs, 16 C.F.R. § 1508.10 (crib manufacturers and importers must maintain inspection and testing records for 3 years) and Customs and Border Protection document retention rule for imported products, 19 C.F.R. § 163.4 (product importers must maintain for 5 years all records relevant for importation, such as product testing and inspection records).

Preserving Your Documents When a Claim is Received, or Litigation or an Enforcement Action is Filed

Document retention obligations may be triggered as soon as a company reasonably should know litigation is likely.

Once document retention obligations are triggered, promptly issue

a document hold order. Content and proper recipients of the hold order will vary under the circumstances.

Ensure the hold order supersedes standard document retention and destruction policies. Pay particular attention to auto-delete policies for e-mails and other electronic data and suspend these policies if necessary.

Collecting Documents in Response to a Claim, Enforcement Action, or Lawsuit

Undertake appropriate efforts to identify custodians from whom documents should be collected. Consider at a minimum:

- Key players in the organization;
- Those known to be involved in the matter; and
- Those specifically identified in a complaint or discovery.

Determining places from which to collect relevant information

Cast a wide net in considering places where potentially relevant information may be stored, including:

- Sources applicable to specific key individuals, such as personal e-mail and individual desktop files;
- Central sources of data, such as file server, shared drives, and Internet-based document repositories;
- Backup and archival systems; and
- Personal storage of highly relevant employees, such as attics and basements.

Once collected, preserve and catalog materials using the method most appropriate under the circumstances.

- In many instances, engaging a document vendor to process and host data on a document review platform is preferable.
- Be careful of metadata and other e-discovery issues.

Maintaining and Preserving Attorney-Client Privilege and Work Product Protections

Legal privilege protections can be lost in many ways, including commonly by:

- Failing to seek legal advice in correspondence with counsel;
- Failing to include counsel in conversations with and among experts; and
- Disclosing privileged materials and communications to third parties not covered by the company's privilege.

An intact privilege can enable a company to:

- Develop litigation or regulatory strategy in confidence;
- Obtain honest and complete information from witnesses; and
- Hear all options from outside counsel and experts.

CHAPTER 4

Front Page Problems: Using Offensive and Defensive Strategies to Protect Your Brand from Reputational Harm in the Press

Hypothetical

A popular parenting blog posts a story discussing how your new, best-selling product – a small indoor swing for babies and toddlers – is allegedly collapsing during use, resulting in injuries to small children. The original post reports only a few occurrences involving bumps and scrapes, without additional injury. The story attracts attention, however, and others respond to report a few similar incidents, one of which involves more serious harm. The blog discussion is circulated widely across Facebook and Twitter, and is eventually picked up by traditional news media outlets. The blog discussion and related press are the first reports you have received of any such problems with your product. You are approaching a period of expected high sales volume, and your biggest competitor sells a similar product but was not mentioned in the blog or the subsequent press.

Issues

Consumer reports of product problems raise a variety of issues, particularly in the age of social media and the Internet. When faced with negative public reports about a product, especially a marquee product, the potential risk of reputational – and legal – harm may be high. Some immediate issues that arise include:

Fact Gathering. Before you can determine how best to respond, it is important to gather as much information about the reported

incidents as possible. What information is being reported? What is the source of the information, and what biases or accuracy issues might impact the information shared? Is the problem a genuine one, or one of false reporting, competitively motivated misinformation, or mistake?

Risk Analysis. After gathering the facts, determine what risks are involved and brainstorm various potential responses. How serious is the reported injury? What is the likelihood of another occurrence? How sure are you of the problem, and what are the costs and benefits of waiting to find out more? What potential financial and reputational impact could result from various corrective actions or inaction?

Message Management. As you determine the scope of the risk and plan responses, develop a communications strategy targeted to address concerns of the various stakeholders. Who within the company will have what information, and when? What information will be given to customers? To retailers? In response to media inquiries? To the general public?

Commercial Impact. If you face competition in the relevant product category consider what impact this media crisis may have on your sales and competitive position. Do other manufacturers have any involvement in the information being reported? Do other market participants face similar risks? Is there any opportunity for joint action? Is there any need for offensive/defensive action vis-à-vis other market participants?

Regulatory Obligations. Regulatory agencies often mandate short reporting deadlines and voluntary self-reporting obligations when certain safety issues arise. Does any agency have jurisdiction over

your product, and if so, do you owe a legal duty to report? What are the risks of failing to timely report? What might be the benefits and risks of reporting even if not necessarily under a legal obligation to do so especially in light of the publicity of the incidents?

Litigation Risk. When product issues attract media attention, they may also attract the attention of the plaintiffs' bar. You should consider developing a litigation defense response plan. Have any lawsuits been brought, or threatened? What protocol will be followed if a complaint is filed? Are there ways to reduce litigation and class certification risks now?

Identify Solutions. If a problem with the product is identified, consider whether to develop ideas for an effective and practical solution that resolves the issue. Engaging technical experts inside and outside the company may be necessary, but proceed with caution in memorializing plans and analyses in writing as these may be discoverable in litigation or by government agencies. In developing potential remedies, weigh the scope of the problem, the population involved, and the desired outcome against the cost and feasibility of potential fixes. In addition, consider how the offered remedy can be communicated effectively and to the right audience to achieve the desired result.

Offensive Considerations

Some offensive steps to consider in developing an affirmative public relations message and crisis response plan may include:

- Issuing your own affirmative press release;
- Publicly identifying flaws in news reports or their sources;
- Publicly identifying flaws in similar products manufactured or sold by others;

- Affirmatively contacting distributors, retailers, and customers; and
- Issuing a safety campaign or other affirmative informational campaign promoting the product and its correct use.

Defensive Considerations

Some defensive considerations to avoid reporting violations, future safety issues, and uncontrolled messaging may include:

- Issuing a litigation hold;
- Developing a strategy for additional testing (either in-house or third-party testing);
- Reviewing the quality control on raw materials, component parts, assembly, and finished product;
- Reviewing design protocol, testing, and safeguards;
- Reviewing prior incident reports for any overlooked information;
- Analyzing regulatory reporting duties;
- Preparing PR responses to press and customer inquiries;
- Developing a possible corrective action (with regulatory agency, if necessary);
- Considering how to ensure corrective action is adequate to resolve underlying issue; and
- Implementing corrective action and follow-up messaging.

CHAPTER 5

Avoiding Reputational Damage During Congressional Investigations and Agency Enforcement Matters

Government scrutiny, whether of an individual firm or an entire industry, is rarely welcome. When it comes, however, it is essential that you respond appropriately and avoid unintended missteps that can have potentially disastrous consequences for your company, not to mention individual reputations.

Most likely, a government investigation will come from one of two places: from Capitol Hill, where high-profile events and good old-fashioned politics may prompt congressional committees to spring into action; or from regulatory agencies, which may monitor industry and inspect firms as a matter of course or in response to external pressures, such as political pressure from the Hill or state Attorneys General offices. Because of their different origins and investigative tools, unique approaches may be warranted when developing an effective response strategy for each while also considering the possibility of responding to simultaneous or "piggy-back" investigations.

Congressional Investigations

Congressional investigations are a hybrid of legal investigations, media events, and lobbying campaigns with procedures and methods unique to the committee that initiates the investigation. Their purpose is usually to investigate and call attention to issues of importance within the jurisdiction of a particular committee. In this way, they are not only

for examination but also incitement. Beyond effecting regulation or enforcement, the goal of a hearing could be to energize consumers, interest groups, or industry, or it could be to embarrass a company or government agency.

An effective response to a congressional investigation should include both a long-term legal strategy and a short-term public relations plan. Not all inquiries result in hearings and not all interrogatories become part of the public record, but it is important to prepare for those possible outcomes. While most congressional inquiries come without the force of a subpoena, a failure to take even an informal request seriously could result in a range of larger problems.

If you receive a congressional request letter, some steps to consider include:

- Demands for documents as well as the scope of questions can and should be negotiated with Committee staff. This will help protect your interests while satisfying the oversight interests of the Committee.
- Seek to avoid exposing trade secrets or other information that demand confidentiality. Committee findings will be made public in all but the most sensitive matters.
- Determine a press and public relations strategy for your company and any witnesses that might be called, in addition to answering Congressional inquiries.
- Develop and always keep in mind the big picture legal strategy.
- Recognize that anything submitted or said in testimony can be used as evidence in a civil or criminal proceeding later.

Agency Enforcement Actions

Usually less dramatic, but no less of a risk to company brands, are agency regulatory actions. They often arise after a violation has been brought to an agency's attention by a routine inspection, a consumer complaint, or congressional pressure.

Some steps to consider in handling agency investigations include:

- Examine your compliance program – make sure you are in compliance with applicable statutory and regulatory requirements before an agency inspection or investigation hits. Don't rely on government investigators to be your compliance auditors.
- Assess and ensure knowledge and control of all aspects of the manufacturing and distribution of your product throughout your supply chain. Require documentation from your suppliers demonstrating they are meeting all applicable regulatory and legal requirements. Maintain detailed records of manufacturing, testing, and sales by batches to facilitate efficient and effective traceability and isolation of products in the marketplace.
- Review your compliance history – make sure you have responded to and corrected any previously observed violations.
- Stay current – standards evolve. What was sufficient for compliance in 1993, or 2003, may not be sufficient in 2013.

Limiting reputational damage during an agency investigation is important given the long term relationship most companies have with their regulator. Some steps to consider to preserve that relationship include:

- Don’t panic, but prepare to respond quickly.
- Be honest with yourself, and prepare to be contrite. Enforcement resources are limited, and though agencies won’t get everything right, they rarely bring actions that are not supported by some evidence of significant violations.
- Retain the appropriate scientific and legal experts. Agencies are data driven organizations. You should consider sharing data to contain and control the investigation. Assess whether you also need manufacturing, recall, and public relations experts.
- Address product in the marketplace – if it poses a risk to consumers, capture it before it causes harm (or more harm).
- Show the government agency and the public that you are on top of the problem and, if necessary, you know how to fix it. Often the difference between brief adverse regulatory events and long regulatory quagmires is whether a company can demonstrate the competence to solve a problem quickly itself, or if the government agency determines that it must step in, supervise, and solve the problem for the company.

Keep in mind that an investigating agency may escalate from informal inquiry to citation to warning letter after a series of investigations or adverse findings, or it may jump directly to aggressive action seeking a civil injunction and other civil penalties – or even criminal proceedings – depending on the severity of the violation. Don’t assume an agency won’t respond dramatically just because it has never taken enforcement action against you before.

CHAPTER 6

Protecting Market Share and Challenging Deceptive and Misleading Advertising Claims by Competitors

Hypothetical

Your company produces and sells Oaties, a leading brand of cereal which has built up customer loyalty over 75 years and has a commanding 70% market share. A new brand of oatmeal, SuperOats, has recently hit store shelves and its advertising states that it is fortified with a proprietary blend of probiotics and natural enzymes. As part of its advertising launch, SuperOats shows a mock taste test, with consumers lining up to try SuperOats and shunning Oaties. The commercial claims that Americans are "switching to the oatmeal that is better for your heart and digestion, and better tasting." Your business believes the claims are false and unsubstantiated. The campaign threatens to erode the Oaties market share just as the back-to-school oatmeal season is getting underway.

Issues

Identify Deceptive Claims. A first step in assessing whether there are legal remedies to stop the damaging advertising is to identify the claims that you believe are false, deceptive, or unsupported by sufficient evidence. You should consider both the express claims and any implied claims that a reasonable consumer would perceive from SuperOats' advertising. When identifying implied claims, consider

whether you need to conduct a consumer perception survey to establish the implied claims that SuperOats' advertising conveys. Whether a survey is needed will depend on what forum you choose to resolve the advertising dispute.

Evaluate the Evidence. The next step is to assess the strength of your legal position by determining what evidence you have, or could obtain, to demonstrate the falsity, deceptiveness, or lack of support of SuperOats' claims. Also, consider whether SuperOats is likely to have sufficient evidence to support its claims. Certain claims made by SuperOats are health benefit claims and will require reliable, competent, and scientific evidence, which under the best circumstances would be reliable clinical data, but in any case would evaluate the product under close to actual-use conditions. Taste preference claims will also require head-to-head testing, adequate sampling, and rigorous techniques.

Assess Legal Options. The final step is to determine which legal options make the most sense based on the strength of your positions, the importance of timing, your budget, and the remedies you seek. You should also evaluate the strength of the evidence you have to support your own advertising claims. Attacking a competitor's claims will necessarily shine the spotlight on your own advertising.

Considerations

The advertisement presents a variety of claims, both express and implied. Some considerations in developing a strategy include:

- Express claims are those that are unambiguous and readily

apparent from the face of the ad. They can be stated in words or conveyed by images. Because express claims are unambiguous, a plaintiff in court can prevail by proving the claim false on its merits, by a preponderance of the evidence. If the plaintiff meets this burden, some courts will presume the falsehood is causing harm, which is a critical component of obtaining an injunction.

- Implied claims are claims that are not expressly stated but nevertheless understood to have been communicated by a substantial percentage of consumers. The FTC and National Advertising Division (NAD) look to how the "reasonable consumer" would interpret an advertisement based on its "net impression," or the totality of the advertising communication. In federal court under section 43(a) of the Lanham Act, a plaintiff bears the burden of introducing reliable evidence proving that an implied claim has been made. This is usually done by introducing consumer survey evidence showing that at least 15% of consumers understood the ad to make the implied claim.
- Only false and deceptive claims that would tend to have a material influence consumer purchase behavior are actionable. Trivial falsehoods are not.

Consider the varying substantiation requirements for each of the claims identified. Under FTC requirements, all claims must be supported by a "reasonable basis," which is a flexible standard that depends on the kind of claim being made. For example:

- *"Better for your heart and digestion."* This is a comparative health benefit claim.
  - Health claims are presumed by the FTC to be material to consumers and held to a high standard of proof. The FTC has held that a "reasonable basis" for such claims consists of "competent and reliable scientific evidence," which means:

Tests, analysis, research, studies or other evidence based on the expertise of professionals in the relevant area that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

  - In recent published orders regarding claims that products treat, cure, or mitigate disease, the FTC has demanded that the advertiser have evidence consisting of at least two, independently conducted clinical studies. In situations involving other health claims (*e.g.*, weight loss), the FTC has accepted somewhat less, such as a single clinical study of six months duration. Studies of the performance of individual product ingredients may not suffice to support claims for the product as a whole, unless it can be shown that there is a reason to believe the product performs exactly the same way, and that the underlying ingredient is consumed in the same dose as in the ingredient study.

- "Americans are switching to SuperOats." This is a brand-switching claim that requires proof that the share gain for SuperOats came from appropriate competitive brand(s). Such claims should be based on consumer preference or sales data, and should not create an unsubstantiated impression of superior product performance.
- Implied taste preference claims. The visuals of the consumers lining up to taste SuperOats instead of Oaties is likely to imply to a substantial number of consumers that SuperOats taste better than Oaties, and that this is at least in part why consumers are switching to SuperOats. It is likely that SuperOats could not prove

it tastes better than Oaties. Thus, if Oaties can obtain evidence of this implied claim (through a survey of consumers), then SuperOats would be required to show that it can support the claim. In general, taste preference claims in national advertising must be supported with a national consumer test of at least 200-250 prospective purchasers. In general, a proper taste test must follow rigorous protocols regarding blinding of participants, handling and presentation of products, and mode of questioning.

The SuperOats advertising can be challenged in many different venues, each with certain benefits and shortcomings and varying evidentiary requirements.

- Section 43(a) of the Lanham Act, 42 U.S.C. §1125(a) creates a federal cause of action for false advertising by aggrieved competitors. Successful plaintiffs can obtain an injunction against the ads, and money damages stemming from lost sales, wrongful profits, and attorneys fees.
  - Such litigation can achieve swift relief, which is critical in many advertising disputes. The remedy is powerful and sweeping, and is an effective deterrent to further false advertising.
  - Because it lives close to the beating heart of the business and marketing function, such a case can be resource-intensive and disruptive to operations.
  - These cases also frequently trigger counterclaims, including for false advertising, intellectual property, and antitrust. Accordingly, discovery by the defendant will likely be intrusive and will focus on sensitive areas such as current and future sales and marketing plans.
  - The risk of bad press is high in such disputes. The media loves reporting on false advertising disputes, and can trigger

substantial consumer fallout if the case is perceived as frivolous or wrong-headed.

- Class actions often follow any finding of liability for false advertising. In one recent case involving a consumer product, 12 separate class actions were filed in the six months after the court enjoined the challenged advertising claims.

- An alternative to litigation is a self-regulation forum known as the National Advertising Division (NAD), which is administered by the Council of Better Business Bureaus. NAD conducts a process by which it hears advertising disputes and issues written opinions setting forth its recommendations.
  - The NAD process is far less expensive than litigation.
  - There is no discovery at NAD, which can be good or bad, depending on how much evidence you have.
  - The NAD process can take 4-6 months, during which period the advertiser can continue to run the challenged claims. Even after NAD issues its recommendations, it is not uncommon for the advertiser to drag its feet regarding compliance. Thus, the process can be frustrating for challengers who seek speedy relief from false claims.
  - NAD has no direct enforcement authority and cannot force a party comply with its decisions. If the advertiser refuses to comply, the NAD will refer the matter to the relevant government agency (most often, FTC) for law enforcement investigation.

- The Federal Trade Commission or state Attorneys General will also consider trade complaints submitted by companies regarding competitor false advertising. Regulators are more likely to act

when there is clear cut evidence of falsity and the deception is likely to harm consumers.

- While the process is less expensive for the complainant than litigation or NAD, it can take a long time to complete, and the complaining party must cede control of the investigation to the investigative agency. Whether the agency takes up the investigation depends on its other enforcement priorities and on its assessment of the harm to consumers caused by the offending ads.
- There is a risk as well that any complaint may trigger a broader investigation by the regulator into business practices in the advertised industry as a whole. Thus, the complaining party needs to consider the risk of drawing unwanted scrutiny from government agencies on its own conduct.

CHAPTER 7

Border Control Limbo: Saving Your Product From Seizures, Forfeitures, Fines, and Delays

Hypothetical

It is mid-November, and you are preparing for peak selling season for your company's line of multi-colored LED string lighting. Your new suppliers in China have assured you that they will come through right on schedule, and you are expecting to receive shipment of 415,000 strings—with over 8 million individual LED lights—any day now for immediate delivery to suppliers across the country. At first, you were leery of changing from your long-time U.S.-based supplier, but the Chinese prices allow your company to sell at a price point that reaches into new and deeper markets. A week before Thanksgiving, you get a panicked phone call from your shipper confirming that the merchandise has arrived in Los Angeles but Customs and Border Protection (CBP) will not release it for distribution in the U.S. You call the CBP import specialist at the Port of Los Angeles hoping for a quick resolution, but you are told to expect delays in processing. The entry has been selected for examinations and review by CBP, and may be detained pending review by the U.S. Consumer Product Safety Commission. CBP indicated that there were multiple errors with the entry and, after all, it's the holidays. At this point, any delay will result in lost revenue, and a significant interruption could ruin your company's performance in the crucial Christmas season.

Issues

Pre-Entry Preparations. Attention to the details up front can often ensure that merchandise will clear U.S. Customs. Did you have the legal right to import the merchandise? Was there another governmental agency certificate or permit applicable to your goods that was required to make entry? Did you comply with all entry filing requirements? Did you hire a Customs broker to assist with entry requirements? Did you obtain a customs bond? Do you have all the documentation necessary to obtain release of your merchandise?

Customs Due Diligence. Familiarity with CBP's procedures on examination, detention, seizure, and penalties can speed your product to market. Do you know what rights the CBP has in examining your merchandise? Do you know how the CBP examination and detention process works? Do you know how long CBP can hold a shipment without issuing a detention notice? Are you familiar with your options for immediate delivery or conditional release? Do you know under what circumstances CBP will execute a seizure? Do you know what merchandise is prohibited or restricted? Do you know what you can expect from a CBP enforcement action? Are you subject to a penalty or liquidated damages?

Resolution with Agencies. Know the customs process or hire a third party with the expertise to resolve your detention issues. Do you know the process for security release of detained or seized goods? What if multiple agencies have jurisdiction over the goods - how do you secure release clearance from each agency? Do you know how CBP penalties can be mitigated?

Considerations

It is absolutely critical that importers properly prepare for the entry of merchandise. The Customs Modernization Act requires that importers understand all of their legal obligations before importing products into the U.S. To be sure they are meeting those obligations, importers may wish to create a checklist for ensuring compliance. Also, importers should confer with customs experts or CBP itself when they arrange for new shipping or when their shipping patterns change so as to avoid unforeseen regulatory impediments and costly penalties. There are often opportunities for importers to save time, money, and headaches by preparing in advance or even obtaining advance rulings from CBP.

Entry Checklist

Right to Make Entry. Do you have a legal right to file the entry for customs clearance and act as the importer of record (*e.g.*, have a financial interest in the import). Have you secured and filed the required import bond? Have you decided to use a customs broker to help clear your shipment, and issued the broker a valid power of attorney? If you are relying on a related business entity to make filings with CBP, what is their ownership interest in your business?

Classification. Do you know exactly what you ordered, where it was made, and what it's made of? Have you provided CBP with the correct tariff classification and duty rate? Do you have a CBP ruling regarding the tariff classification?

Value. How will you establish value for the shipment? Will it be based on price paid on an invoice and the terms of the sale? Is the seller "related" to you? Are there additions to customs value

related to the import that do not appear on the invoice but must be declared to CBP (*e.g.*, commissions, royalties, assists, or packing costs)? Is the valuation based on a CBP ruling?

Origin. Are you importing merchandise duty-free under a free trade agreement or special tariff classification? If the product involved manufacturing steps in multiple countries, did you verify that the country of origin was correct and that the requirements for the duty-free treatment have been satisfied? Have you correctly marked the merchandise's country of origin? Is your country of origin determination based on a CBP ruling?

Invoice. Have you filed an invoice with CBP? Is the invoice complete in accordance with CBP regulations? Is it correct?

Other Compliance Issues. Are there any other documents you need to file? What do other government agencies (OGAs) require? Does the importation of the subject merchandise necessitate any special tests or certifications? Are there special security, enforcement, or other interests in the type of goods that you are importing of which you should be aware? Is release of the goods subject to a separate OGA filing and release?

OGAs that work with CBP to monitor, detain, and seize goods at the border include:

- Consumer Product Safety Commission
- Department of Agriculture
- Food and Drug Administration
- Fish and Wildlife Service
- Patent and Trademark Office
- Environmental Protection Agency
- Alcohol and Tobacco Tax and Trade Bureau

Companies engaging in regular importation should develop and implement a robust system of internal controls to avoid customs violations. Basic customs training should be mandatory for employees who work in procurement, sales, logistics, and tax. Additionally, customs compliance should be integrated into importers' systems to ensure that customs considerations will be addressed as a matter of course. Importers should be constantly monitoring the shifting landscape of CBP regulations to anticipate new hazards and to exploit emerging opportunities.

Key Internal Controls and Examples from the Customs World

Control Environment. Is your senior management committed to import compliance? Has senior management established policies and directives requiring production, development, purchasing, accounting, supply chain, logistics, and other departments to establish internal controls to determine ensure customs compliance?

Risk Assessment. Have you analyzed your risks related to imports? What products have the highest duty? What products are subject to tariff preference claims (*e.g.*, free trade agreements)? Do you import from related parties? Do you have consistent suppliers in low risk regions of the world? Do you have processes to analyze import risks and reduce such risks?

Control Activities. What controls do you have in place to protect your company from risk? Do you have written import compliance policies and procedures? Have you designated responsible employees for import matters? Do you train employees on import risks and laws? Do you have processes to ensure compliance when changes in the supply chain occur?

Information & Communication. Do all employees and managers involved in the importation process understand the importance of compliance with CBP regulations? For example, are there processes in place to ensure that a post-shipment pricing change due to defective units in the shipment is reported properly back to CBP? Have you established a mechanism to keep these employees apprised of best practices? Do you have processes to notify employees of changes in the law? Do you have controls and processes for communication and oversight of third party service providers in the supply chain (*e.g.*, customs broker controls)?

Monitoring. Do you have written procedures for monitoring the accuracy of claims made to CBP (*e.g.*, post entry audit process)? Do these procedures require corrective action and changes to existing processes if errors are discovered?

Even the best prepared importers can run afoul of CBP, so they should always prepare for the worst. CBP routinely inspects and detains shipments, and works with OGAs before releasing shipments into U.S. commerce. It is important for importers to understand the inspection and detention process, and importers should work with customs experts to devise detailed and realistic crisis management plans. Also, it is important for importers to understand benefits or prior disclosure to avoid penalties if the importer (rather than CBP) discovers an error.

Entry Process Timeline

Importers should understand the following timeline for the entry process:

Pre-Entry (ISF) Filings. An ISF filing with CBP includes 8 required

details about the imported product (*e.g.*, classification, origin, supplier). ISF filings in most cases are made 24 hours before the products are exported. In addition, importers and carriers must prepare or have other documents before importation, including an entry manifest, evidence of the right to make entry, evidence of a bond, a commercial or pro forma invoice, a packing list, and any other documents required by OGAs.

Entry. This is the physical arrival of merchandise into U.S. customs territory. Entry filings are made prior to arrival or upon import, and final entry summaries (with legally binding claims on duty assessment and admissibility) are due within 10 days of import.

Inspection. Upon arrival, CBP has the right to examine the merchandise. CBP has 5 working days to determine whether the merchandise will be detained, released, or seized.

Detention. If CBP does not release the merchandise at the end of the 5-day period, the merchandise is considered to be detained. CBP must provide importers with formal notice of and reasons for detention.

Seizure. If the merchandise is deemed to be brought into the U.S. contrary to law, then it may be seized.

Release. If CBP does not seize or detain the merchandise, then it will be released into the U.S.

Request for Redelivery. When CBP conditionally releases merchandise and subsequently determines that the merchandise is inadmissible, it may order the redelivery of the merchandise. Redelivery must be requested by CBP within 30 days of entry.

Liquidation. When duties are paid on merchandise, they are considered "deposits" until CBP makes a final assessment. Once CBP makes that assessment, the duties are "liquidated," and CBP can issue a bill for underpayment or a refund for overpayment. Liquidation typically occurs 314 days after entry, and must occur 1 year after entry unless extended by CBP.

Penalties. CBP may impose penalties, and seek past duties owed (even if the entry is liquidated), if an importer makes an error in connection with one or more entries. The statute of limitations on penalties and past duties owed on customs entries is 5 years. The penalty exposure can be significant (multiples of the duty loss and up to the domestic value of the imported goods). CBP also may impose liquidated damages on importers related to any breach of the customs bond, which requires importers to provide complete, accurate, and timely CBP filings, and to redeliver goods upon request.

CHAPTER 8

Minimizing Your Exposure to Class Action Litigation

Hypothetical

Your company, PestCo, is a leading manufacturer of agrochemicals. After years of multi-million dollar research and testing, PestCo began selling Grub-Away, an insecticide that is highly effective at killing grubs, a persistent and destructive lawn pest, at very low rates of application. The testing that PestCo conducted and submitted to regulatory agencies shows that Grub-Away is non-toxic to mammals, grass, flowers, trees, and shrubs. Shortly after product launch, PestCo began to receive numerous reports from homeowners around the country that, following application of Grub-Away to their properties, other plants on their properties are dying at alarming rates. The Internet buzz is that class action lawyers are lining up clients, and PestCo may soon be facing class suits in both state and federal court.

Issues

Design Away Risk. Pre-launch steps to design away risk may have ensured that Grub-Away was safe and effective. Did it adequately test Grub-Away, and document the results of all the tests? Did it comply with all of the regulatory requirements before introducing Grub-Away into the market? Does Grub-Away's label adequately warn of the risks associated with using the product?

Gather the Facts. Consider what factual investigation is needed to have command of the facts and make strategy decisions on key litigation defenses. Is there a way to investigate the product reports that won't be discoverable in litigation? How can PestCo investigate this issue without creating documents that will lay out the case for a class action for plaintiffs' counsel?

Message a Response. How should PestCo respond to the reports it is receiving? What should customer service representatives say when disgruntled homeowners call? Should PestCo pull Grub-Away off the market? Should it launch a coordinated claims process?

Provide Adequate Relief. Will any risks persist even if PestCo settles? Can claimants come back again if they are later unhappy with their settlements?

Considerations

One of the best ways for PestCo to minimize its exposure to class action litigation is to prepare for such litigation during product development. Before PestCo sold its first bottle of Grub-Away, it should have identified and complied with any regulatory or licensing requirements; tested the product to ensure efficacy; identified and evaluated potential risks associated with the product (including those associated with foreseeable misuse of the product); and made considered decisions about what risks to address in the product label and associated product materials. A lapse in any of these areas opens a door that a smart plaintiffs' class attorney will exploit.

PestCo will need to carefully structure and conduct any investigation to ensure that it does not create evidence that will be used against

the company in class litigation. At the outset, PestCo likely needs to conduct an internal investigation to determine whether these complaints have any merit and, if so, why this issue was missed in the product development process. The last thing PestCo wants to do in conducting such an investigation is connect all the dots for plaintiffs, and lay out the class action case in a discoverable memo. Accordingly, PestCo should take special precautions, including consulting with and involving counsel, to ensure that it preserves any and all privileges applicable to both the investigation process and any documents that may be created and disseminated as a result.

PestCo needs to customize a response that takes into account litigation risks and business concerns. Just because a certain response has worked for a competitor, or with a prior PestCo product, does not mean it is going to be right for responding to Grub-Away complaints. Further, anything and everything done will need to be carefully vetted, planned, and scripted to ensure that messaging is consistent and does not inflame customers and their counsel, which may cause them to be more likely to sue.

Defend Against the Litigation. PestCo may choose to stand behind Grub-Away and defend against any class actions that are filed. A number of early strategic decisions will shape the course of such litigation: Should Grub-Away seek to bifurcate merits and class discovery? Should it proceed with merits discovery with an eye toward defeating the case on the science without briefing class certification? Should it conduct additional product testing, and run the risk of creating bad evidence? The answers to all of these questions will depend on the facts of the case, and in particular how strong of a defense the pre-launch product stewardship provides.

Launch a Claims Process. After investigating the issue, PestCo could decide that its business is better served by pulling the product and launching a voluntary process to pay claims for yard damage. This may be because PestCo discovers that Grub-Away actually is responsible for the damage customers are reporting. Or, PestCo may deem the litigation and reputation costs of defending and continuing to market the product too steep. Depending on the complexity of the claims and number of claimants, such a claims process could be time-consuming and expensive to design and implement, and it would not prevent plaintiffs' counsel from filing class actions. If successfully run, however, a voluntary claims process can cut the legs out from any attempt to certify a class. This is because the plaintiffs likely would not be able to show that a class action is the superior method of resolving the matter, which is a prerequisite to class certification under federal law and the laws of many states. If the product involved were different and regulated by a federal agency such as the FDA, CPSC, or NHTSA, a consumer level recall done in cooperation with the agency would provide similar advantages in thwarting class action claims.

A settlement doesn't always mean that a claim is closed forever. Should PestCo choose to settle claims, either through its own claims process or through a class action settlement, it would need to use care to minimize the possibility of claimants "reopening" their settlements in the future. Reopener plaintiffs could allege that PestCo improperly withheld information and defrauded them into accepting a lower payment than they otherwise would have. Or, if the settlement resolves class actions that are filed, reopener plaintiffs could allege that PestCo and class counsel conspired to lower the payment to the class members in exchange for greater attorneys' fees. Reopener litigation has the

potential to be more costly than any initial suits, as plaintiffs in such cases often assert claims under RICO or parallel state statutes that have treble damages provisions.

ABOUT OUR PRODUCT RISK MANAGEMENT GROUP

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Crowell & Moring's Product Risk Management Group offers a unique, multidisciplinary approach to businesses in identifying and managing the legal risks of advertising, marketing, distribution, and sale of their products and services. Our lawyers and policy professionals help clients navigate the complex legal and regulatory regimes, both domestically and internationally, applicable to the design and promotion of their products and services as clients develop strategies to grow their businesses. The Product Risk Management (PRM) Group assists clients in taking innovative and proactive measures to protect their business from the array of challenges before them, from regulatory investigations and tort litigation to false and unsubstantiated claims by competitors. Clients report that our practice is one of a kind in its holistic, innovative, business-oriented, and end-to-end approach to risk management and mitigation.

To help companies meet these myriad challenges, our team includes lawyers and professionals from our offices across the United States as well as in Europe, and brings deep knowledge in the wide range of necessary legal fields this work requires — including advertising, marketing, and consumer protection, such as false advertising litigation; defense of government enforcement proceedings; privacy and data protection; sweepstakes and promotions; indemnities and warranties; chemicals and environmental; import/export; sourcing, supply chain, and distribution; trademark and intellectual property; product safety; reputation and crisis management; and defense of consumer class action and products liability litigation. This enables us to handle the full range of commercial and regulatory legal issues facing our clients in a comprehensive and integrated approach focused on mitigating risk.

Our Approach

Address the full lifecycle of our clients' innovations. We partner with clients to develop comprehensive risk evaluation and early warning systems to reduce lifecycle costs for existing and new business ventures. Our experience, and the experiences of our clients, confirm that well-structured, front-end investment in these systems consistently produce significant cost savings and the avoidance of lawsuits and claims over the life of the products and services our clients create, sell, and support. When challenges are lodged, our clients are better prepared to defend them. We team clients with our experienced advertising and tort litigators and trial lawyers, as well as regulatory and prevention counselors, to develop programs and processes that envision how government regulators, courts, and opposing counsel may characterize events months or years in the future.

Embrace regulatory authorities. Our clients do not run and hide from regulatory agencies or from tort or regulatory legal requirements. Instead, they build good will and trust with agency officials over time. Crowell & Moring regularly helps our clients meet regulatory authorities and come to know them. Over and over, as other regulated entities suffer fallout from "run and hide" strategies, our clients build on the trust they have developed to avoid adverse agency action.

"Become" our clients. We work intensely to build knowledge and understanding of our clients' products, industries, corporate philosophies, business goals, and strategies, then tailor our legal advice and representation to our client's needs and personality. We often come to serve as their institutional memory when it comes to developing new areas of business and evaluating a business idea's legal history and track record.

Understand, then achieve, victory. We learn early how our clients define "victory" in the potential outcome of their legal challenges and direct our counseling, litigation, and regulatory efforts accordingly. We can think of no occasion in which a Crowell & Moring client has expressed displeasure in our handling of an advertising or product risk management matter, or in the outcome we helped our clients to achieve.

Be mindful of costs. Our clients tell us that we fret about legal costs as much as they do. We can field a diverse team of PRM professionals, each possessing varying levels of experience and offering corresponding rates, enabling us to manage product matters efficiently and cost effectively.

ABOUT CROWELL & MORING

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Crowell & Moring LLP is an internationally recognized, full-service law firm with offices in Washington D.C., New York, Los Angeles, San Francisco, Orange County, London and Brussels. We are known for our world-class Government Contracts practice, in addition to our leading practices in Antitrust, Intellectual Property, Litigation, International Arbitration and Health Care. With nearly 500 attorneys, we represent major businesses, governments, and other organizations – both public and private – in high-stakes litigation, complex regulatory and administrative matters, and government and internal investigations.

Crowell & Moring's lawyers are both counselors and litigators. We advise our clients on the wide range of issues that result from and impact their business activities. And we have litigated many significant cases before administrative agencies, state and federal trial courts, courts of appeal and the Supreme Court. We carefully tailor our advice to each client, calling on our superior knowledge and experience to help predict how an agency or decision maker will react, and helping them plan accordingly.

In addition, our lawyers have unparalleled experience and expertise establishing and reviewing corporate compliance and other internal audit programs. Indeed, Crowell & Moring developed the government contract compliance review more than 25 years ago, and we have applied that expertise for nearly three decades on behalf of companies and organizations doing business with federal and state agencies. In addition, we have adapted this long-standing expertise into services for insurance reviews, corporate compliance, employment audits, product risk management audits, health care, and many other areas.

As our client, you will have access to a wide range of advisory and

litigation services as our lawyers and professional staff collaborate on your behalf, forming multi-disciplinary teams to meet each legal and business challenge. To do this, we draw on expertise from our Antitrust, Corporate, Insurance, Health Care, White Collar, Environmental, Labor and Employment, and other practices, as well as from our international trade consulting affiliate, C&M International.

In addition, Crowell & Moring has a strong reputation as a law firm that works well in a team environment. For example, we have a very successful practice serving many clients as National Coordinating Counsel for major litigation. This requires us to work with and manage the activities of many different attorneys and law firms throughout the country.

In both education and experience, our lawyers come from diverse backgrounds that enable them to offer premier service to all clients. Many different nationalities and more than 20 different languages are represented on our legal staff. Many of our lawyers and specialists have held significant positions in government service before joining the firm.

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