Partners for Outsourcing Carry Special Risks
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The benefits of outsourcing are too great for product contamination scandals to decrease use of the practice. Companies outsource to reduce costs; to reduce or control personnel; to reduce overhead and improve performance; and to better focus on the core business by finding somebody who can pay more attention to a specific process. The challenges are the same as always.

While the drivers behind outsourcing affect almost every industry in the same way, drug and device industries have the responsibility to outsource and to control outsourced suppliers and outsourced materials in a way that meets their regulatory responsibilities. Drugmakers and device manufacturers also have unique, heightened risks.

Accordingly, finding the right partner or vendor in the drug or device industry can be more complicated than it is for other industries. Finding a partner to do business with means finding a vender that fits with the organization. That means documenting the prospective vendor's:

* Ethics and morality;

* Integrity standards;

* Mission statement;

* Quality management policies and purposes;

* Maintenance procedures for products; and

* Understanding of its quality responsibilities.

Selecting a Partner

The first step in selecting a partner is to find out if it can live up to the standards it has set, particularly the regulatory requirements. Potential vendors should receive a written description of the company's expectations and have a chance to read what the company expects of itself and determine whether they want to be involved. These statements should be clear and concise.

The company can then measure the potential partner against those standards to determine if it can provide the necessary service within the parameters that have been established.

The FDA holds management, not the quality assurance department, responsible for outsourcing. Management must have selection processes for evaluating all potential partners, including suppliers and subcontractors, a defined corrective and preventive action process, risk analysis procedures and clearly defined regulatory compliance processes. The standards a company has to comply with should be established and communicated to all outsource partners.

Potential partners also should have established their own ethical and moral standards, goals and mission statement. The company must do more than just read what the vendors have put on paper -- it should see if they actually live up to what they say they do. This examination is not a typical independent audit done by an external company that comes in for a few days, reviews only the

papers, compares them to what the auditor's concept of a standard is and says, "Okay, everything is in order because it's all written down." Rather, the company's goals and standards have to be lived, they have to be documented and there needs to be evidence that shows they have been adhered to. The fit has to be one not only of paper and words, but also of the way the company operates.

Outsourcing partners have to understand and be willing to comply with regulatory requirements. They also have to understand that when the regulators advise a course of conduct, drug and device companies often take that advice as more than just a recommendation. Potential partners also have to understand and accept some regulatory risks -- legal action could be taken against them, for example, and regulators can detain and prohibit their products from entering the U.S.

The question of whether the products can be imported can have a negative impact on how much the contractors will manufacture. That kind of holdup can be caused by other contractors, by problems with the manufacturer or by all kinds of situations that are not necessarily within the outsourcing partner's control. They need to understand they are subject to the entire supply chain and the events that surround it.

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Congress and the FDA Make Note of Industry Responsibility
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From the FDA's perspective, manufacturers are responsible for their products. However, with the heparin case stirring up Congress, some changes in that perspective may be on the way. The FDA will likely place greater burdens on both manufacturers and the companies to which they outsource.

In testimony before the Senate, Alastair Wood, a Cornell University professor of medicine and pharmacology, said manufacturers need to take stronger steps to ensure the integrity of their supply chains -- a responsibility he says goes beyond meeting regulatory requirements. According to the New England Journal of Medicine, he went on the say, "Neither adulteration of drugs and food products nor the use of lead in toys can be prevented solely by regulators; prevention requires intense supervision by responsible manufacturers."

It is not the job of the FDA or any regulatory agency to assure the quality of a company's supply chain from top to bottom. The agency is responsible to the American people for making sure the industries it regulates abide by rules and regulations and have an adequate supply of products that comply with the regulatory needs and requirements. But even if manufacturing is contracted to someone else, the primary responsibility lies with the manufacturer, the entity regulated by the FDA.

The agency's focus is changing, however. The FDA's Janet Woodcock, also testifying before a congressional committee investigating the heparin contamination, said that all parties throughout the supply chain -- from brokers, distributors and importers to finished product manufacturers -- can and should be held responsible for their activities (see related story).

This approach is not a change in the government's thinking. The FDA has never said that everybody is not responsible. In the past, it said it typically will focus on the people it can reach through its enforcement activities. The FDA has a broad reach, but it doesn't necessarily have the procedures and the regulations in place to change that reach or to fulfill all expectations in the modern world. However, Woodcock's testimony before the Senate may result in some changes to give the agency more regulatory authority.

Sen. Edward Kennedy (D-Mass.), in his comments at that hearing, echoed the call for industry to be more responsible, saying that companies "should be required to know more about the firms from which they obtain their ingredients and audit them for ongoing compliance." Like many members of Congress, he pointed out that the agency does not have the resources to properly oversee all outsourcing. With the FDA asking for help and Congress listening, it is reasonable to expect that the agency will look more into how companies are evaluated, how they are selected and how the auditing and monitoring processes are carried out.

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Managing Partners and Validating Their Work Is Key to Outsourcing Compliance and Success

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The FDA lives by the rule that everything can be outsourced except responsibility. The deaths associated with contaminated heparin and the ensuing investigations and recalls have underscored the need for firms to be diligent in ensuring suppliers are performing in accordance with regulations and manufacturing specifications.

But heparin is only an extreme case that captured headlines around the world. The FDA is routinely warning companies for issues related to outsourcing, and the message is always the same: If it's the company's product, the company is responsible.

In March 2008, the FDA announced it was seeking a $2.2 million penalty against a California hearing aid manufacturer for violations of federal law, including manufacturing standards violations and the failure to notify the FDA of a change in an outside supplier or vendor, which may have exposed recipients of the devices to unnecessary health risks. The company, Advanced Bionic, was accused of good manufacturing practice violations, including failing to sufficiently evaluate and select a new vendor as the supplier of a critical device component, and failing to adequately validate the continued safety and effectiveness of the hearing aid by testing lots under actual or simulated use when the unapproved vendor's component was used.

Advanced Bionics never accepted the FDA's assertions, but the company agreed in July 2008 to pay $1.1 million and its CEO agreed to pay $75,000.

But the key is that the problems stemmed from vendor selection and vendor monitoring. Monitoring is as crucial as picking the right outsourcing partner. Even after a vendor has been thoroughly vetted, it may provide products that are not up to the company's specifications. A company should have mechanisms in place that monitor partners and validate new components from new vendors.

Also in March 2008, Retro-Tech, a Dallas-based maker of wound dressings, received an FDA warning letter for several problems related to its use of a contract manufacturer. The alleged violations included:

* An unsigned purchasing procedure, written during the FDA's inspection of the facility, did not require an evaluation of potential suppliers, contractors and consultants;

* The firm did not maintain a list of purchasing data or documents describing product requirements, specifications and quality expectations for its wound dressings being manufactured at contract facilities;

* Retro-Tech did not document the results of its evaluation of its contract manufacturing facilities' ability to meet its requirements; and

* The firm did not establish quality system procedures outlining the responsibilities and manufacturing operations for each of its contract manufacturing facilities before receiving its first production lot from the manufacturer, packager and sterilizer.

The first item highlights the importance of validating outsourcing partners. Because the document was written while the inspection was ongoing, it is safe to assume it was put together hastily. In addition, it's possible the agency would have objected whether the procedure included the missing elements or not.

The second item demonstrates that if a company can't show its documented purchasing requirements, the FDA will assume there are none. Without identified, documented requirements, the company cannot validate the process or the product -- a serious charge for the FDA to make. Lack of such requirements also makes it impossible for the outsourced contractor to validate its work because there is nothing to validate against. Retro-Tech probably had requirements, but the issue of whether they were established properly is a clear problem.

Documentation also is the subject of the third item. The FDA said the firm "did not document the results of its evaluation of its contract manufacturing facilities' ability to meet its requirements." The implication is that the company conducted an evaluation, but it wasn't documented. However, the FDA does not distinguish between the two. As far as an inspector is concerned, if it isn't documented, it didn't happen. The agency expects companies to have everything relative to vendors documented.

The fourth item from the warning letter is another case of the company failing to have written quality requirements and clear, defined expectations -- a perfect example of what can go wrong when a firm begins outsourcing without its eyes wide open.

Often, problems like these don't turn up in FDA inspections. They sometimes can be perpetuated over years until something happens in the process and the company starts receiving a product that doesn't meet its poorly defined requirements. Unfortunately, it can take a recall -- or worse -- for everyone involved to recognize their original outsourcing decisions may not have been done in the best possible way.

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Potential Pitfalls -- And How to Avoid Them
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To avoid headline-grabbing disasters like heparin, companies need to make sure they avoid some common mistakes.

An outsourcing partner may change processes, personnel, location and ownership without notifying the contracting company. Sometimes a contract specifically calls for notification, but if the vendor violates the contract and fails to notify the drug- or devicemaker, the manufacturer may be unaware of process changes that negatively affect the product. A company must monitor its partners and maintain a close relationship with them so it will know when key aspects of manufacturing or reporting processes are changing, even if they have notification requirements built into their contracts.

Often, when something goes wrong, a contractor's excuse is, "That wasn't in the contract." The contract must be tight, and everyone involved should understand what is and isn't important. Proper vetting of potential outsourcers can ensure a good contractor that will tell its partner about situations that need to be addressed, not just ignore problems that may or may not be specified in the contract.

Vendors should be aware enough of the regulations and the requirements of the industry to say, "The company should be looking at this because it is a pertinent part of what it needs." Vendors may have to be educated in those areas, but they should view their role as helping to ensure quality, not just following the contract. If they do not view their role that way, they may be companies that do not operate within the ethical framework that was laid out during the selection process.

What About Data?

The outsourcing partner likely will have a large amount of data and will know a great deal of information about the contracting company. In worst-case scenarios, a vendor has withheld data, and contracting companies have not been allowed to access them. Vendors should make all data about a product available to the contracting partner that is selling the product, both for regulatory and nonregulatory purposes.

In addition, data held by contractors should be maintained in a manner that is compliant with regulatory requirements and meets established standards for such matters as confidentiality. (In the U.S., when the FDA talks about regulatory confidentiality, it means product data and patient data, typically in the area of clinical investigations. Regulatory bodies in other parts of the world are more focused on confidentiality in a broader sense.) Access to the data is important as well, since the data are needed to set up monitoring processes.

In the case of a company outsourcing as much as 75 percent of its products to suppliers, there will be a large amount of data, especially from inspections and certifications. The company would want to see the data, but its partners would not want to be burdened with the obligation of constantly packing up and sending them. A vendor's position may be that data are available when needed for a specific purpose, but trusting that approach may be unwise.

In that situation, a company should look carefully at the kind of data that are important, based on what the control points are, and focus on what happens when a quality decision has to be made to continue or modify a process. Narrowing focus on the crucial data can cut down on the amount that needs to be transmitted. The company also can implement an automated system the collects needed data through a computerized mechanism and is routinely available. While this process may be the ideal solution, it requires an additional investment.

Staying Out of Trouble

Diligent audits are a key tool, but not the only tool, for detecting problems with vendors. An audit is a snapshot in time, but it doesn't guarantee compliance over time, which makes diligent monitoring even more important. A good audit is just an assessment of the quality assurance program, not an assessment of all the products. Monitoring provides information about outsourced products, but audits need to be constructed in a way that targets the relevant data.

Once the relevant data are identified, they need to be reviewed on an ongoing basis. Expectations and agreements have to be spelled out in writing for outsourced suppliers to know what data to provide and how frequently they need to be looked at.

Outsourcing partners must be trained on the requirements the company expects them to satisfy. It's not enough for training to be specified in a contract; partners have to clearly understand what the requirements are that must be taught and the regulatory requirements they are fulfilling in the role of surrogate. That understanding may require them to retrain their employees, and since all companies have turnover, the training will have to be an ongoing effort. The company should

monitor vendors' personnel and structural changes to know when vendors have made alterations that might affect obligations under their agreements.

A company should constantly measure compliance with regulations, contract agreements and expectations, including the regulators' and public's expectations of the products.

Supplier Oversight And Monitoring

Monitoring of suppliers needs to follow the same framework as monitoring of all processes. It should be based on defined processes and understood risks. The FDA thinks of risk relative to patient, product and process, in that order. But industry has more risks than regulatory liabilities. Business risks may involve the costs, the supply and the ability to meet the requirements of other, non-FDA demands.

Since risks change over time, they have to be reviewed and assessed constantly. A new process should rarely have the same risks a couple of years after it's implemented as when it began because those risks have been mitigated and new liabilities may have emerged. There may be some residual risks. But by controlling, monitoring and improving processes, many of the risks can be eliminated over time. The FDA will always look at risk and how firms control it, especially as it relates to outsource partners.

Establishing effective monitoring begins by establishing the key process data about performance. The company will want to monitor from the critical control points -- places where the company can intervene to impact a process and to help control the process.

Once the critical control points are established, the company must watch them, at least remotely, to see if the outsourced partner's operations are in a state of control. Monitoring at the defined control points will help prevent problems, but it will require well-defined processes, well-defined risks and good technology.

Agreements with outsource partners should include clearly defined roles and responsibilities that specify what actions will be taken in response to problems identified through monitoring. It will be especially crucial during the first year of operations and following changes, since those are the times when gaps in processes are likely to come to light through monitoring.

Every individual should understand how the corrective and preventive action (CAPA) system works. No one should ask if something should be put in the CAPA system because everyone should know when an event occurs if it should be submitted as a CAPA. In describing what CAPA actions are, it is highly recommended to use the FDA's definitions.

When Something Goes Wrong

Regardless of how well run a company is, there will be out-of-specification results, recalls or complaints. Suppliers must know what those terms mean and what is supposed to occur when those events happen. Outsource partners need to know what their role will be in response to these incidents. They need to understand that an investigation will take place and that people from both companies will be participating in the investigation. Further, partners need to understand the type of investigation that will take place and what the expectations will be for their participation.

To handle nonconformance in a predefined, established way, the company needs clearly defined responsibility for the initial investigation. It's important to know who is going to do the investigation within the outsource partner because it typically has to begin there. Responsibility for determining root cause, follow-up and CAPA also must be established, and issue closure must be clearly defined and assured. Failure to find the root cause and inability to document that an event has been closed effectively are two of the fastest ways to bring the wrath of the FDA.

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Not Every Activity Can Be Outsourced
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In choosing partners for outsourcing, companies should know the parts of their operations that they are not willing to outsource.

Most companies have developed a technology and process for a particular product and have the expertise in-house for maintaining those technologies and processes. For such new technologies, there may not be sufficient expertise outside the company to safely transfer the process to an outsource partner. If processes are outsourced, an adequate plan must be made for training and overseeing employees at the outsource partner. However, the burden of doing this often will make it impractical to outsource.

Any activity that cannot be monitored should not be outsourced. Sometimes, distance will make it impossible to monitor a process, and sometimes no expert will be available to monitor the process. Regardless of why monitoring cannot be accomplished, companies should recognize its importance when they consider outsourcing.

Specific Commitments

It also is dangerous to outsource activities that involve specific commitments to the FDA, Justice Department or other government agencies. If the FDA expects a company to take certain actions in a certain way, it will not like seeing that function outsourced without keeping the agency informed. The company must consult with the agency and establish that the reasons for outsourcing are scientifically based. The agency will not necessarily be sympathetic to business needs to outsource -- cost cutting or other financial reasons -- but it will recognize scientific needs.

When a company outsources a process or a product, it often decides to downsize its quality assurance department on the assumption that the contractor is handling those responsibilities. But when companies move to outsource, the quality assurance department is the one area that should increase in size. Monitoring a partner is generally more difficult and time consuming than monitoring an internal operation, especially when outsourcing major operations. Essentially, some of the production or processing capabilities are traded for the need to monitor what external suppliers are doing.

There is no general rule or specific full-time-equivalent requirements per supplier to determine the number of quality assurance employees. It depends to a great extent on what is being outsourced. For example, many companies have outsourced IT, generally an area where the quality department has not been involved. But because it's being outsourced, partner companies now need to be audited. Companies that outsource some of the manufacturing of pharmaceutical products may not do as much testing in their own laboratories, and they may require more personnel to inspect labs and audit their activities than when the laboratory work was in-house.

A company should pay attention to such issues because, at least in the beginning of the outsourcing relationship, there likely will be some bumps in the road.

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FDA: Manufacturers Responsible for Outsourced Drugs
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The FDA has repeatedly said during the past 18 months -- since Congress took the agency to task over contaminated heparin from China -- that it holds drugmakers responsible for contaminated drugs when they outsource production of ingredients to other countries.

Last year, for example, responding to questions during a Senate Health, Education, Labor and Pensions Committee hearing in April, Center for Drug Evaluation and Research (CDER) Director Janet Woodcock said the drug industry needs to be held accountable for the quality of drugs it markets.

"It is no coincidence that drug ingredients produced in countries with weak safety standards are often contaminated," Sen. Sherrod Brown (D-Ohio) says in a statement at the time of the hearing. "The FDA must immediately review pharmaceutical outsourcing and make necessary changes to keep American consumers safe."

As a result of testimony heard at the hearing, Brown asked Pfizer and Merck to provide information regarding their outsourcing operations. In a June letter to Gerald Migliaccio, a vice president at Pfizer who testified at the hearing, Brown asks how much the company saves by outsourcing.

Congress Explores the Issue

"At the hearing, you testified that 17 percent of Pfizer's active ingredients and drug product manufacturing is outsourced. You stated that 'competitiveness and cost is a driver' of these activities. At that time, I asked you how much Pfizer saves each year by outsourcing and you said that you could research that question and get back to me. I am following up now to ask you for that figure," Brown writes.

Noting that the company has responded to all written questions from senators at the hearing, Pfizer provided Brown with examples of the technologies it outsources for which it has limited or no internal capacity.

Those services, the majority of which are purchased from locations in the U.S. and Europe, include prefilled syringes and inhalation devices, freeze drying manufacturing services, specialized packaging, soft gelatin capsules and active pharmaceutical ingredients for biotech drugs, the company told FDL.

CDER's Office of Compliance (OC) has highlighted the agency's efforts to examine the drug supply chain, reiterating regulations that say the NDA holders are responsible.

"Ultimately the dosage form manufacturer with its name on the label is responsible," the OC told FDL when asked the best way to hold firms accountable for the safety of drug components. "Our regulatory structure under the [Food, Drug and Cosmetic] Act, and implementing regulations, provide for the identity, strength, quality and purity of the drug and the prohibited acts provide for civil sanctions and criminal penalties for failure to do so."

"In light of the question on how to deal with incidents such as heparin, sourcing ingredients, testing and [control of the] supply stream ... are important elements FDA and other regulators are examining and encouraging industry to focus on to prevent such incidents (e.g., the recent guidance about [diethylene glycol] in glycerin, testing to detect in order to comply with cGMPs)," the OC said.

The office also highlighted the revised International Conference for Harmonisation (ICH) Q10 Pharmaceutical Quality Systems guideline, which describes a model for an effective system. Its recommendations complement ICH Q8 pharmaceutical development and Q9 quality risk management guidances.

The harmonization guidance notes that the model is "intended to encourage the use of science- and risk-based approaches at each life cycle stage, thereby promoting continual improvement across the entire product life cycle."

The guidance outlines three main objectives for the model:

* Achieve product realization;

* Establish and maintain a state of control; and

* Facilitate continual improvement.

The guidance also stresses the need for the use of knowledge management and quality risk management -- including the development of a quality manual -- for the model to be implemented correctly. Both the ICH's final version of the guideline and the FDA's guidance include language relating to outsourced activities.

Pharmaceutical companies are "ultimately responsible to ensure processes are in place to assure the control of outsourced activities and quality of purchased materials," the guidance says.

When product ownership changes, pharmaceutical companies should consider the complexity of the situation and ensure that the ongoing responsibilities are defined for each company involved and that any necessary information is transferred, it says.

The "Guidance for Industry: Q10 Pharmaceutical Quality System" is available at www.fda.gov/cder/guidance/8515fnl.pdf[http://www.fda.gov/cder/guidance/8515fnl.pdf].

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Carefully Written Contracts Are Key to Success
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As important as outsourcing is to improving a company's bottom line, a badly written or incomplete contract or service agreement will cause more harm than good. While all of the following items may not be appropriate for every agreement, a company should consider these factors when negotiating with a vendor or partner:

Definitions. Everyone needs to speak the same language to each other and to the regulators.

Scope. The extent of responsibilities in the agreement has to be stated and clear.

Conditions and limitations. Most agreements include carve-outs for each side, often in the form of risk-shifting or indemnification clauses.

Key contacts. Agreements must do more than state that duty X will be performed by function Y. The names of individuals and their responsibilities should be identified. The partner should not be relied on to decide whether those people are capable of doing what is required of them.

Reporting and documentation requirements. Everyone should completely understand all requirements of applicable regulations.

Change management. The process of requesting, evaluating, planning and implementing change to a system needs to be included in the agreement.

Property. Both physical and intellectual property need to be addressed.

Secrecy and confidentiality. The meaning of confidentiality varies around the world, so it largely depends on who the regulators are and to whom the products are being supplied.

Duration. In contracting, the exit opportunities and the chances to make changes and improvements to the agreement should be evaluated, not just the duration of a contract.

Arbitration. Most contracts and service-level agreements address when and how arbitration will be used to settle disputes.

Infrastructure. Infrastructure needs to be specified and included in audits and monitoring activity. Often, companies ignore the infrastructure or take at face value their partners' representations about it, but never monitor or check to make sure that it's maintained the way it should be.

Service delivery. Timing and quality measures are important for service delivery. The contract should include escalation processes for deviations from its requirements. If on-time delivery becomes a recurring problem, the contract should spell out corrective measures. Automatic actions should be built into the contract and tied to each aspect of service delivery.

Support. The manufacturer, contractor, contractee, outsource partner or any outside entity could provide support for the administration of contract operations. Qualifications for support providers may need to be spelled out.

Regulatory requirements. In addition to ensuring rules are understood, all parties must understand agency expectations that have sometimes informally developed outside of the rulemaking process.

Validation requirements. Fundamentally, validation is nothing more than good science, and the FDA may expect a validation plan or report. Any potential partner's validation efforts should fit the company's needs, beliefs and structure. If necessary, a company can train partners in how validation needs to look to avoid the possibility of FDA inspectors finding out that the company is making the product, or some percentage of it, using one set of standards and processes and its outsourcing partner is using a different set.

Delivery of documentation. Documentation -- who retains it, who has access to it and how is it going to be accessed -- is part of the monitoring process, making access to it key. The contract must clearly define who will have access to the data and when that access will occur. Ideally, documentation will be stored electronically, allowing for remote access and constant monitoring.

Business continuity. Disaster recovery, storage of information and routine backup of data should be included in a contract.

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Disclosure of Outsourcing May Be Required
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In some cases, the FDA requires manufacturers to disclose use of contracted partners. Frequently, such disclosure is part of a condition of approval, or it may be a required step for some submissions to the agency. Also, firms must notify the FDA when they make substantive changes of their contracted partners. The down side is that, by alerting the agency, it may look at the contractors and decide to audit them. However, the FDA often does not have the resources to conduct these kinds of audits. In fact, the agency is stretched so thin, it rarely has a chance to read all the information submitted to it. The agency staff's approach tends to be more like triage.

Disclosure also is made in a number of informal ways, such as during inspections, discussions and meetings. The FDA often finds out about contractors during routine audits and similar activities. In some cases, the outsourcing partner has to register with the FDA, such as when a company performs a significant manufacturing operation like contract sterilization. Because contract sterilizers are considered by the FDA to be manufacturers in their own right, many are inspected more routinely than their clients. Congress may look to extend the FDA's authority in this area by requiring more firms to register with the agency.

However, the FDA has the authority to inspect most, if not all, of a company's outsourcing partners. It simply lacks the resources to do so.

A company also can outsource to itself. The practice is common, but it's not a shield against liability. If a company outsources, for example, the servicing of its equipment to another division it owns, the FDA looks at the activity as being within the same company.

In the heparin case, a number of subsidiaries were involved, but the FDA focused on the company it directly regulated. The lesson is that a company cannot shield or protect itself from liability by outsourcing to itself or by purchasing through subsidiaries. The FDA can still make its case against the manufacturer, resulting in penalties and negative attention.

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