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[MDDI Article Index](#)

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Q&A

The Modernization of ODE

Former ODE Deputy Director for Science and Regulatory Policy Phil Phillips helped streamline the way CDRH handles premarket submissions and interacts with industry. He's now able to try to effect change from the outside.

[Erik Swain](#)

Few people understand the medical device premarket review process better than Phil Phillips. After a 24-year career at FDA during which he rose to the number-two position at CDRH's Office of Device Evaluation (ODE), Phillips is now able to share his experience with industry in a consulting role. Earlier this year, he retired from FDA and joined **Becker & Associates Consulting Inc.**



Phil Phillips

(Washington, DC) as director of its medical device practice. Issues he will work on include FDA jurisdiction and compliance, device classification and evaluation, clinical trials, human-subject protection, product labeling, postmarketing surveillance, and device promotion and advertising.

While at CDRH, Phillips was responsible for helping design and implement a number of changes to regulatory policies and procedures. Much of the center's effort to adopt "least burdensome" provisions went through him. He also played a large role in crafting a number of the dispute resolution processes CDRH now offers to industry. And he spearheaded CDRH's attempts to regulate the reprocessing of single-use devices in as fair a manner as possible. These are just a few of his contributions to the modernization of medical device regulation. For his efforts, he received two Distinguished

Service Awards from HHS and three FDA Awards of Merit.

Like few others, Phillips has the authority to assess the changes ODE has gone through over the years and analyze the challenges that remain. He spoke to *MD&DI* East Coast Editor Erik Swain in May.

Q: You spent 24 years at FDA. What were the most significant changes FDA underwent during that time, especially concerning ODE?

A: When I joined the device program back in 1981, device regulation was still pretty much in its infancy. The agency was facing an increasing workload. The numbers of applications were growing by leaps and bounds, and I was part of a significant hiring effort to bring in additional review scientists. When the Medical Device Amendments were passed, Congress gave the agency little direction on how to implement them. During those early years, there was an intense effort to add structure to device regulation. For example, the concept of substantial equivalence was not initially defined. Everyone involved seemed to have a slightly different perspective about what constituted substantial equivalence. To foster consistency, we had to define substantial equivalence and establish criteria for decision making, as well as [write] standard operating procedures. What we created became codified in law in the Safe Medical Devices Act of 1990.

In general terms, the evolution in device technology produced tremendous changes for FDA. For example, when I first arrived at FDA, lasers were used basically for ablation or cauterization. Now they are sophisticated surgical instruments used for delicate procedures, such as reshaping corneas in refractive surgical procedures. That is a significant evolution in technology within just one device type; there are many other examples.

Q: How well are ODE reviewers able to keep up with the latest developments?

A: Keeping pace with technology has always been a challenge for CDRH. Millions of dollars are spent in R&D, and much of that work is veiled in confidentiality. This information is not available to FDA scientists. That puts them at a significant disadvantage. The agency knows very little about the research ongoing in the device industry. That's why there's

such a steep learning curve when new technology appears in marketing applications. Having said this, reviewers do remarkably well. The recent influx of graduates helps, along with more training dollars, as well as more training opportunities for reviewers. Even without additional resources, there have been some rather creative efforts to keep pace with technology. A site-visit program was established to get reviewers out into manufacturers' facilities so they have an earlier look at significant R&D activities. There are also vendor days, where companies come in to FDA with exhibits. There may be 5–20 medical device companies that travel to FDA to let agency scientists look at the latest advances in their technology.

Q: Has the user-fee act of 2002 (MDUFMA) given ODE the resources it needs to do its job?

A: Yes, significant resources have resulted from MDUFMA, but keep in mind not all user fees come to ODE. ODE is principally where all premarket activity occurs, but the Office of In Vitro Diagnostic Device Evaluation and Safety does premarket review too. The Office of Compliance evaluates the manufacturing section of original PMAs and supplements for changes in manufacturing. The Office of Surveillance and Biometrics does statistical reviews. The Office of Communication, Education, and Radiation is involved in labeling and human factors aspects of reviews, and the Office of Science and Engineering Laboratories may bring its expertise to premarket activities as well. Given all this, where have the MDUFMA resources gone? There needs to be greater accounting for how MDUFMA resources are allocated and used in CDRH. Some may disagree, but it's too easy to get involved in review activities without regard to the necessity of your participation or the value that you are adding. It may be beneficial to have everyone log the time they spend reviewing submissions, so there is a record of everyone's contribution. Then we would have a better handle on what resources are [being] used in the review of different applications.

I'm not the only one who thinks that should be done. Industry seems to like the idea, and it needs to be explored. How much does it really cost to review an original PMA application or 510(k)? In the early days, we had a mechanism to get a better handle on how review resources were spent. Now it's not as complete. The center has a time-reporting program, but it's a snapshot in time and does not tie review efforts to

specific applications. If CDRH were to go a bit deeper, it would probably reap a lot more reward.

Q: How well has ODE adjusted to MDUFMA's review-time goals?

A: ODE did not really need much of an adjustment period. Historically, ODE has taken timeliness very seriously. From the beginning of the device program, leaders and managers at FDA believed timeliness of reviews was a significant facet of protecting and promoting the public health. So time goals are not really new to ODE. I think ODE has done extraordinarily well so far. The staff has worked very hard to implement the user-fee program, from collecting user fees to making the decision-making process more transparent so the outside world can see how FDA makes decisions. The staff developed numerous guidance documents to help achieve its goals in a very short period of time.

Q: What sort of practical changes occurred as a result of MDUFMA?

A: Additional resources and new procedures comprised the largest changes, but some subtle changes have occurred within the program areas. For example, in the original-PMA arena, there historically have been "licensing PMAs." When one company received an approval, it would allow another company, for a fee, to have access to its PMA to create a separate PMA based on the original. This happened with frequency, and with no changes in the product, except for a few labeling changes. After MDUFMA, these sorts of PMAs have been subject to full user fees, resulting in a decrease in companies licensing their approved PMAs. I do not know if this is good or bad, but it has occurred as a result of fees.

When a reviewer receives a 510(k) that represents a change to a legally marketed device, there is less of a tendency to tell the company that [its] submission is not necessary.

Admittedly, this area can be confusing, and a company may conclude that a submission is required when it is not. If the submission is unnecessary, most likely it will be reviewed and [the product will be] found substantially equivalent, with the user fee being collected. This is a subtle shift in the way business has been done, but a significant one that can be attributed to user fees.

Q: You were involved with the efforts to bring

premarket review to reprocessed single-use devices. How well has ODE handled that challenge? What, if anything, remains to be done?

A: ODE and CDRH have done a very reasonable job of fulfilling the requirements and expectations related to reprocessed SUDs. I believe they have completed their review of all the sterilization validation submissions required under MDUFMA. They will be able to review additional device types in the future, and I see no reason why they will not be successful. Given the issues that FDA has encountered, it would not surprise me if the agency looked closer at other device types.

One comment I have from a regulatory perspective is that more needs to be done to level the playing field between OEMs and the reproprocessors. The changes that I believe are in order would affect both sides. For example, reproprocessors are required to provide in-depth sterilization validation data in premarket submissions. OEMs do not, because sterilization validation is addressed through quality systems for them. On the other hand, OEMs are expected to have process controls in place to identify changes in the composition of materials from their vendors. This is facilitated because the OEMs have access to needed information through their relationships with their suppliers. But reproprocessors have no business relationships with those suppliers. OEMs often make subtle changes that may make their products very different from a reprocessing standpoint, and the reproprocessors may not know. So significant gaps remain, even after the statutory changes that have occurred.

Q: In the Kessler era, ODE and the rest of FDA were perceived as anti-industry. In recent years, they've been perceived as more industry-friendly. With recent congressional and public criticism of FDA, there is concern that the pendulum may be swinging back. To what extent does political pressure have an effect on ODE?

A: Many of my FDA colleagues may disagree, but politics has very little bearing on FDA review organizations. At the higher end of the agency, politics probably plays a more significant role, but at the ODE level, I found very little effect. There is a tendency when politicians express interest in an area to attribute future events in that area to politics, even when the

events have nothing to do with politics. In my opinion, the effect of politics on FDA decision making is a bit overplayed.

I will agree that the pendulum governing industry-agency interaction swings over time. The more interaction that exists, the more FDA is perceived as industry-friendly. But congressional oversight is only one factor that can affect the pendulum. There are other institutions that can also have an effect. The Office of the Inspector General and the General Accounting Office are two that come to mind. Also, the leadership at the agency can certainly influence its regulatory posture.

On an optimistic note, there are now laws in place that will likely prevent a dramatic shift away from a healthy level of FDA-industry interaction. With the FDA Modernization Act, the agency's mission was adjusted. It is now charged with promoting public health, as well as protecting it. International harmonization has become a priority, as have outreach activities. In accordance with the statute, the agency is now charged with consulting with stakeholders, and that means industry, consumers, and professional organizations. That requirement has had a significant effect.

On the device side, opportunities for early collaboration and interaction have been built into the regulatory system. FDA is now mandated to have meetings before and during the review process. The CDRH ombudsman has been introduced. Several new dispute resolution procedures, including an advisory panel, were created. After all these statutorily based changes, curtailing productive interaction with industry will be difficult for anyone, even the politicians.

Q: How well has ODE adhered to "least burdensome" principles? How has that worked in practice?

A: From a broad program standpoint, least burdensome principles have been implemented reasonably well. If you look at the de novo risk-based classification program and the center's guidance development program, lessening regulatory burden is a key principle that drives them. De novo classification has been extended to 29 different types of devices that, if not for that classification opportunity, would have been placed in Class III, subject to PMA requirements. That is a considerable reduction in regulatory burden, with no reduction in assurance of device safety and effectiveness.

Also, a significant part of the center's guidance development program is to ensure that the agency is not establishing overly burdensome expectations for industry.

Unfortunately, with individual applications, there is less success in achieving a least burdensome regulatory approach. More people are involved, and all may view least burdensome in a slightly different light. So, with individual applications, there is more of a tendency to deviate from least burdensome principles. Unfortunately, least burdensome remains a term that is misunderstood by FDA personnel and industry alike. Too many people think it encumbers FDA from getting all the information it needs for decision making. Nowhere has that been suggested. Least burdensome simply challenges agency scientists and regulators to maintain an open mind and to consider alternative ways that have less regulatory burden to address situations. All alternatives should receive serious consideration.

Q: How would you characterize ODE's relationship with the Office of Combination Products (OCP)?

A: OCP is in a difficult position. Let's face it; it is difficult to find solutions when in a tug-of-war between agency components. It seems that combination products either attract or repel interest. Some combination products have such significance that the centers want to exercise jurisdiction over them. But some are of little interest, and no center is clamoring to regulate them.

Having said that, [OCP Director] Mark Kramer is a great person to lead in the combination products area. He is from CDRH, having been a scientific reviewer, a branch chief, and the director of the center's staff college. He has a very good relationship with CDRH. He is very knowledgeable about device regulations and his presence has been good for all, but it has been particularly good for the device industry.

Q: Where do you see regulation of combination products going in the next few years?

A: Combination products will remain a significant challenge for all parties involved. Combination products are the wave of the future, especially for devices. As we find more biologicals and pharmaceuticals that alleviate problems associated with device use, we will encounter more products that combine

these into one system. Devices with pharmaceuticals and biologicals represent sophisticated technology for FDA to analyze, making the agency's regulatory process much more complex. Establishing an organization within the Office of the Commissioner to address this task was a wise move. OCP will probably take a much more active role in getting these products through the FDA system.

Q: What advice would you give to a firm that is submitting an application to ODE for the first time?

A: One important responsibility is to do your homework. Things have changed a tremendous amount over the years. The availability of information about a firm's regulatory responsibility is dramatically different from 30 years ago. You can go to the Internet and get volumes of information on all aspects of FDA regulations. You should know how to use the FDA Web site, retrieve information, and pull it together. There are other resources. DSMICA [Division of Small Manufacturers, International, and Consumer Affairs] does an absolutely outstanding job assisting small manufacturers. The program operations staff at ODE can provide consulting services to companies navigating the different premarket program areas. Companies should take advantage of opportunities to interact with FDA when it is in their interest. Many manufacturers do not have the opportunity to come to Washington to meet with FDA, but good interaction can be accomplished by the telephone or by electronic means. In many cases, so much information is available that direct interaction is really not necessary. If you are facing complex issues such as clinical trials associated with IDEs and PMAs, or preparing a humanitarian device exemption, then it is much better to reach out and see if FDA has any suggestions before you commit to study designs or expensive research activities.

Q: When a firm's regulatory personnel get to meet with ODE, what questions should they be asking?

A: The questions will depend on the individual's situation. There is no standard list that should be addressed. They will also depend on the type of interaction. Pre-IDE submissions will raise certain types of questions; 100-day meetings for a PMA application will raise other types. In general, you should prepare for whatever issues are causing you concern. Be respectful of agency scientists' time, as staffs are pulled in a lot of different directions. I recommend submitting materials

in advance of meetings. Call to talk with the branch chief or team leader after materials have been received to see if ODE has questions. These simple steps may lead to a more-productive interaction. If you suspect the meeting will be contentious, I recommend alerting the CDRH ombudsman, Les Weinstein. Les attends a number of meetings with industry and he interacts in a very nonthreatening way. If you reach out to him, he makes every effort to be accommodating.

Q: What will be ODE's biggest challenges in the next few years? How should it approach them?

A: Training employees, supervisors, and scientists in the principles of responsible regulation. In the next few years, there will be an exodus of many seasoned regulators from FDA, primarily due to retirement. A large number of new people will have to be brought in and properly trained. I have always advocated a systems approach to regulation. All of the regulatory programs, from quality systems to premarket review, are interrelated. FDA must have a cadre of scientists and managers that understand all the different regulatory systems and are able to put them together in a way that makes sense. FDA is going to need more generalists with this ability, and generalists have always been in short supply and are too often underappreciated. Getting the right people in positions of responsibility is how to address and provide solutions for the complex problems that are just over the horizon.

Q: What do you hope to accomplish in your new role as a consultant?

A: I wish I had more consulting experience, so that I would know whether my expectations are realistic. When I was with FDA, my greatest satisfaction was derived from resolving conflicts and making sure regulatory requirements were reasonable. I hope to continue to offer reasonable solutions to regulatory challenges to industry, as well as FDA. We all want the same result: safe and effective products reaching the market in a reasonable and predictable time frame. As long as that is everyone's focus, we should experience success. As clients come to me with various scientific and regulatory issues, I hope to assist them in my new role as much as I did when I was with FDA.

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