IACP Board of Directors Meeting

2010

Legislative/Regulatory Options for IACP in 2010

Possible Options/Issues for IACP Action in 2010

Please note that IACP will continue to work on issues of concern to the pharmacy community, such as intrathecal legislation, amending the Congressional health care bills with regard to the definition of manufacturing, DXM legislation and other issues as they impact compounding pharmacists.

- FDA Reform (Amendment to Section 503 (A) – Addressing the issue of FDA regulation of compounding and the IND process (please see below for additional detail and background on the issue);
- Credit Card Fees (Interchange, Service Fees, contracts, etc.) for compounding pharmacists – working with card issuers and legislators on the issue;
- Medicare reimbursement of compounded medications (amending the Social Security Act or pursuing action through CMS);
- Promotion of Compounding (Through Legislation) as a Key Component of Personalized Medical Solutions;
- Partnering with another Medical Group for a Mutual Legislative Fix on Issues Related to Access of Compounded medications to Certain Patient Groups; and/or
- Other Items for Discussion as Proposed by IACP Board Members.

For all of the suggested issues listed below, please remember that the following options are available to IACP to pursue on each issue. We have elaborated on the proposal for a legislative fix to clarify definitions and regulatory authority over compounding (the 503 B fix).

As for the other suggested issues, there are additional options available through regulatory channels, as well.

- Option A: Concurrent Resolution
- Option B House or Senate Committee Report Language
- Option C: Appropriations Process
- Option D: Bill/Legislation
- Option E: Executive Order
- Option F: Congressional Letter/Dear Colleague
- Option G: Oversight Hearings
- Option H: Regulatory Reform/Adjustment

FDA's Involvement in Compounding Regulation:

As drafted, the IACP-endorsed legislation, an amendment to 503(a) of FDAMA, addresses the very definition of compounding and outlines FDA regulatory jurisdiction (limited), adverse event reporting, positive/negative lists, emphasizes the role of State Boards of Pharmacy and more. Essentially, the draft legislation aims to establish a clear and well-defined statutory "fix" to what is and is not legal in terms of compounding and the regulation of the practice.

However, there are differing views as to whether IACP should "upset the apple cart" (given that the FDA has not issued any warning letters to pharmacies or doctors in 2009 on the issue of estriol) or to pursue clarity, regardless of the possible outcome (that clarity may or may not be what IACP wants). It appears that FDA has chosen to "stand down" this year on the issue of estriol IND enforcement.

IACP has checked with House and Senate staff to see if FDA reform is likely in 2010. In 2009, Congress enacted some FDA reform with regard to food safety. However, Congress did not address the issue of drug reform and that remains on the table. Although FDA reform is not a high priority in 2010, it is still a possibility, which makes it incumbent upon IACP's Board to make some strategic decisions in an effort to guide staff on the association's priorities in 2010. 2010 is also an election year for the entire House of Representatives and 1/3 of the U.S. Senate.

There are a number of options to pursue to attempt a resolution to the dilemma that the various court opinions have produced on 503 A.

Option A: Concurrent Resolution

A concurrent resolution is not equivalent to a bill and its use is narrowly limited within these bounds. The term "concurrent," like "joint," does not signify simultaneous introduction and consideration in both Houses. This approach does not codify the language contained within the resolution, but is simply kept as part of the Congressional historical record.

Pros:

This is a somewhat innocuous approach to getting the estriol issue aired before Congress. It helps Members and their staffs familiarize themselves with compounding pharmacy/FDA issues. It also allows a Member of Congress to co-sponsor the bill to show their support for the issue, but does not obligate that Member to supporting an actual statutory change. In other words, it is a good way for legislators to support a cause without having any future repercussions, as there is no change to the actual law.

Cons:

The "downside" is that there are no real "teeth" to a concurrent resolution. Since the resolution does not change law, it does not provide a real remedy to a problem that is statutory or regulatory in nature. In addition, Members of Congress who co-sponsor a concurrent may be too "tapped out" to also sponsor something that will change the statute by pointing to this as their effort to help compounding.

Although it is certainly possible to have both a concurrent resolution and a bill on an issue, it would drain staff and grassroots support if there are two separate bills to work on the same issue.

Outlook for Vehicle Success in 2010 (fair at best):
The likelihood of getting broad bi-partisan support is more likely in the House than the Senate at this point. A resolution would still bring recognition to the issue and to the problems with the FDA. This option could be helpful to IACP in terms of "buying time" until the political climate is more favorable to FDA reform legislation

Some IACP members seem deflated by a perceived lack of success of this approach. Introducing a new resolution that takes a heavy lift of both staff and member time for only a handful of sponsors may be risky.

Option B: House or Senate Committee Report Language

When bills are considered by a committee, notes or "report language" are often added to the record to provide additional details about the intent of the statutory language and issues deliberated.

IACP could attempt to get accompanying language inserted into a report of any germane piece of legislation moving through the House or Senate that would clarify the "intent" of Congress on issues relating to the FDA. To be of help, the conference report language must remain intact throughout the conference report deliberations and ultimate approval.

Pros:
The conference report option gives IACP the opportunity to more clearly define the problem to Congress and allows Congress to "go on the record" on the specific compounding pharmacy issue. It also helps future legislative or regulatory efforts when referencing something passed by Congress and the related report language in terms of setting a precedent. This option could be pursued simultaneously with other solutions and does not limit IACP's other attempts to remedy the problem. This option can often be pursued "surgically" if desired, and does not require broad support.

Cons:
Again, this option is non-binding and does not carry the weight of statute. So, any success on this front will have a limited impact on the FDA's current activities. It does not provide a solution to the problem, but rather an opportunity to highlight it and to show the support of the House and the Senate of IACP's cause.

Outlook for Vehicle Success in 2010 (Fair):
Given the fact that Congress may consider FDA reform measures, but it doesn't rank highly on their "to do" list for 2010, the opportunity to successfully obtain bill report language (conference report) is fair.. Many Hill offices have suggested the approach.

Should IACP pursue this route, it could lessen the chance of obtaining statutory changes made in a similar bill at the same time ,although it lays the groundwork for future legislative language changes to the statute.

Option C: Appropriations Process

Congress annually considers 11 or more appropriations measures, which provide funding for numerous activities including general government operations such as the administration of federal agencies.

Appropriations measures are under the jurisdiction of the House and Senate Appropriations Committees. *Regular appropriations bills* provide most of the funding that is provided in all appropriations measures for a fiscal year, and must be enacted by October 1 of each year. Appropriations measures are usually for year-long periods, thus requiring authorization for the new calendar year.

IACP has considered appropriations riders in the past such as asking Congress to put a "limitation" (or condition) on the agency's spending. A limitation could be as simple as "the FDA shall not expend any of the Congressionally appropriated funds on enforcement of its IND requirement for estriol."

Pros:
Again, this option could be helpful in "buying time" until the political climate is more favorable to compounding legislation. Additionally, this type of action can send a clear signal (if the funding is tied to the FDA and related agencies appropriations bill) that legislators are watching the agency closely on an FDA issue (compounding pharmacy/estriol enforcement in our case). It can also send a signal that legislators might be willing to cut back the agency's budget if changes aren't made at the FDA (or other targeted agencies). Also, there are options of attempting to directly cut funding to the agency, asking Congress to put a "limitation" (or condition) on the agency's spending or adding a Congressional directive to report language. Many of IACP's strongest supporters (in Congress) are on these two committees.

Cons:
The biggest challenge with this approach is the fact that appropriators are always hesitant to pull funding for an agency without a compelling reason. Additionally, no citations were issued by the FDA in 2009 on the issue of estriol, thus making this option less necessary. In addition, adding language to an appropriations bill is often regarded as an attempt to 1) legislate through an appropriations bill and/or 2) add a limitation on the bill. Neither is well regarded and most appropriators are very opposed to passing authorizing changes on an appropriations bill as a procedural issue. This effort would also be only a temporary "fix" to the problem – one year – for as long as the appropriations bill is valid. In addition, it often takes a great deal of lobbying and substantiation of claims made to get a legislator to add a limitation (also known as a condition on spending) on an appropriations bill.

Outlook for Vehicle Success in 2010 (Poor):
Although we have some of the biggest supporters of the compounding pharmacy community on the House and Senate appropriations committee, this is definitely a difficult proposition in terms of procedural objections.

Option D: Bill/Legislation (Specifically FDCA 503(B)—IACP's model legislation

This memo does not intend to speak to the merits of IACP's new model legislation—503(B). Rather, we describe here that 503(B), comprehensive compounding legislation, would fix a number of issues if passed.

A bill is the vehicle used for most policy making, whether permanent or temporary, general or special, public or private. It would replace FDAMA 503A and would provide pharmacists with an explicit exemption from FDA approval and FDA manufacturing requirements as long as the compounding was done within the parameters of the 503B. Specifically related to estriol, the legislation allows compounding from ingredients that have a USP monograph and thus estriol would be allowed to be compounded and dispensed pursuant to a valid prescription. This would apply, as well to other compounded medications with a USP monograph.

Pros:
Pursuit of a legislative solution is likely a good long-term solution to the estriol and other problems at the federal level. Such an effort would have a binding statutory effect should it be passed by the House and Senate and subsequently signed into law by the President. This would have the effect of eliminating existing policy on estriol (e.g., court rulings, FDA CPG) in favor of the new statute.

IACP has friends in Congress who seem interested in having IACP pursue this route and IACP staff has continued to meet with key House and Senate staff to discuss legislative concepts. Such legislation could clarify the existing landscape of FDA jurisdiction and confusion left by the 9th Circuit Court and 5th Circuit Court decisions.

In addition, IACP's huge grassroots base could help effectively gather co-sponsors to this legislation and provide contacts in many Congressional districts.

Cons:
Any statutory change would engage (fully) all of our opponents in a fierce and public debate. It would be critical that IACP ensure that the whole pharmacy community is "on board" for such a law change and be prepared to combat our opponents. In addition, there is always the strong possibility that the language we begin with may not be the language with which we finish. There is even the possibility that we encounter such substantial changes that IACP would need to oppose the final proposal. When pursuing a legislative change, opponents (and allies) can crawl out of the woodwork. IACP must be prepared for all possibilities.

IACP and its members have laid a great deal of groundwork with key Senate HELP committee members and key House Energy and Commerce committee members. This work has developed some good, strong bipartisan allies on compounding issues for IACP. It is IACP's hope that these legislators will weigh in heavily on behalf of IACP on the issue.

Outlook for Vehicle Success in 2010 (Fair, at Best):
With the new make-up of Congress and the Administration, it will be a difficult proposition to push through quickly. Rep. Henry Waxman (D-CA), who chairs the House Energy and Commerce Committee which is the committee of jurisdiction over FDA, has (in the past) been on the side of further regulating the practice of pharmacy compounding. Chairman Waxman has a history of anti-compounding positions and correspondence/legislation to that effect. However, on the Senate side, newly appointed Chairman of the Senate HELP Committee (Senator Tom Harkin, D-IA) is more amenable to weighing the issues facing compounders on this front. IACP has worked to establish a good relationship with Senator Harkin and his staff and would hope to work with them on a collegial basis toward some reform of FDAMA. Senator Harkin has not yet expressed a position specifically on 503A (503B) of FDAMA.

There are a fair amount of "unknowns" when it comes to moving this bill in a Democratic majority Congress, in terms of where legislators will position themselves, especially in an election year.

Option E: Executive Order

An "Executive Order is a rule or order that is issued by the executive branch of the government and has the status of a law – would be uniformly enforced federally.

Pros:
This approach would not require any Congressional activity nor would it require Congressional approval. If the Administration were willing to address the estriol issue via Executive Order, it would typically take far less time and energy than it would to enact legislation. There would be no (prior) hearings to the action and could be done at the Administration/agency level.

Cons:
IACP would not be able to rely on its grassroots network (a substantial and strong force) to help with this pursuit. This would solely be done at the Administration level and Congress would not be involved. Additionally, this approach would likely serve a short-term solution to put an initial stop to the FDA's activities with regard to estriol, but would not be a complete or permanent solution to the problems created under FDAMA. Additionally, the Administration would likely seek input from the FDA prior to issuing such an order. FDA has traditionally held contrary positions to IACP on the issue of estriol and INDs.

Congress and administrations have typically been averse to opposing FDA on issues relating to drug safety and efficacy (which FDA will argue is the case with estriol). Congress and administrations do not typically want the exposure associated if data were to become available indicating a problem with the drug. It would require a heavy dose of Administration lobbying to see a proposal of this nature through to a successful finish. It would remedy the situation, but only for the duration of the Order.

Outlook for Vehicle Success in 2010 (Unknown):
It is hard to say where we stand on an Executive Order on this issue. However, IACP is putting all of its tools in place to pursue this option, should it be deemed viable. If successful, it would "stop the bleeding" for compounding pharmacists for the near future.

Option F: Congressional Letter/Dear Colleague

A Congressional "Dear Colleague" letter to a Congressional Office-produced letter sent by one member to all fellow members (of the House or Senate) on an issue of importance or on legislation that may about to be or has been introduced. Dear Colleagues usually describe a new bill and ask for cosponsors or ask for a member's vote on an issue.

However, Dear Colleagues can also be a great way for a Member of Congress to show his or her support for the IACP cause. While it is more a matter of PR than a solution, it helps in the effort to make the issue more public.

There is also the option of having a Member of Congress who is supportive of the compounding pharmacy community to send a letter to the appropriate agency (in this case, the FDA) expressing their views and/or concerns.

Pros:
These letters are generally fairly attainable in terms of finding a Member of Congress who is willing to write a letter to the FDA or a Dear Colleague. One of these letters can certainly help to raise awareness of the issue or to help sway the votes of another member on an issue. It can also help gain momentum for an issue that may be moving through Congress. These letters also give the agency an indication of how Members of Congress may feel about an issue or where future legislation on the issue may be directed.

Cons:
The only real downside to these letters is that they do not change things definitively nor do they have any real impact on the issue in terms of a solution. The timing is also important with these letters. Once a letter is sent out, your allies and opponents will have a heads-up on your issue and how (in some cases) you plan to proceed.

Outlook for Vehicle Success in 2009 (Good):
Estriol has already been the subject of a number of Dear Colleague and letters to the FDA on both sides (pro and con) of the issue. Many of the inquiries sent by Members of Congress to the FDA have simply gone unanswered on the estriol issue. Those letters that have been answered are largely viewed to be meaningless and lacking in the information

Option G: Oversight Hearings

Each standing committee, other than the Committees on Appropriations and on the Budget, is required to review and study, on a continuing basis, the application, administration, execution and effectiveness of the laws in the committee's jurisdiction and the organization and operation of federal agencies and entities having responsibility for the administration of those laws.

The purpose of the review and study is to determine whether laws and the programs created by Congress are being implemented and carried out in accordance with the intent of Congress and whether those programs should be continued, curtailed or eliminated.

Pros:
This effort could do a great deal to unveil many of the problems at the FDA and with the FDA IND requirement. Much of the casework that has been submitted to IACP could be shared with the appropriate committee for responses from the FDA. These hearings are a good way to substantively highlight the many (and depth of) problems at the FDA on the estriol IND issue. IACP also has many allies in Congress who have expressed a willingness to hold FDA oversight hearings on the issue of pharmacy compounding and estriol. The FDA would be forced to come to testify and answer the questions submitted by any Member of Congress.

Cons:
There is no guarantee that the initial focus (goal) of the hearing will remain intact. The hearing could turn and ultimately be an airing of anti-compounding sentiments from Members of Congress who agree with the FDA. In addition, the FDA could also reveal at these hearings any information it may have that puts compounding pharmacists in a negative light. IACP can provide the relevant information going into the hearing, but there is no guarantee that the outcome of the hearing will be positive for compounding pharmacists.

Outlook for Vehicle Success in 2010 (Modest):
Oversight hearings on the FDA are highly likely in this Congress. Those hearings will cover a broad array of FDA issues. If IACP decides to go this route, it is important to ensure that compounding (FDA reform and the FDA's interpretation of and enforcement of FDCA) is kept as the focus of these hearings. IACP would likely bring in individual pharmacists or physicians who have experience with the FDA and its implementation and enforcement of the IND requirement.