

FEDERAL TRADE COMMISSION

Public Workshops and Roundtables: Emerging Health Care Competition and Consumer Issues

AGENCY: Federal Trade Commission

ACTION: Notice of Public Workshops and Roundtables and Opportunity for Comment

SUMMARY: The Federal Trade Commission (“FTC” or “Commission”) announces it will hold two workshops and roundtables in the fall of 2008 on emerging health care competition and consumer issues. They will focus on two distinct areas in which competition and consumer protection policies are implicated: (1) competition provided by developing an abbreviated regulatory approval pathway for follow-on biologic drugs; and (2) competition among health care providers based on quality information. The workshops and roundtables will be held at and administered by the FTC and their dates will be announced in a separate public notice.

This notice poses a series of questions for which the FTC seeks public comment. The Commission will consider these comments as it prepares for the public workshops and roundtables. In the spring of 2009, the FTC will release a report that analyzes the potential impacts on the marketplace of various policy options in these two areas.

DATES: Specific dates for the workshops and roundtables will be announced shortly, along with an agenda. Comments on the questions contained in this Notice must be received on or before September 30, 2008. In addition, any interested person may submit written comments to any of the topics addressed during the workshops. Comments

directed at a particular subject considered in a workshop or roundtable must be received no later than 30 days after the date of that workshop or roundtable.

ADDRESSES: Interested parties are invited to submit written comments electronically or in paper form. Comments should refer to “Emerging Health Care Competition and Consumer Issues – Comment, Project No. P083901” to facilitate the organization of the comments. Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with Commission Rule 4.9(c).¹ Comments should not include any sensitive personal information, such as an individual’s Social Security Number; date of birth; driver’s license number or other state identification number or foreign country equivalent; passport number; financial account number; or credit or debit card number. Comments also should not include any sensitive health information, such as medical records and other individually identifiable health information.

Because paper mail in the Washington area, and specifically to the FTC, is subject to delay due to heightened security screening, please consider submitting your comments in electronic form. Comments filed in electronic form should be submitted by using the following weblink: <http://secure.commentworks.com/ftc-healthcarecompetition> and following the instructions on the web-based form. If this Notice appears at

¹ The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission’s General Counsel, consistent with applicable law and the public interest. See Commission Rule 4.9(c), 16 CFR 4.9(c).

<http://www.regulations.gov>, you may also file an electronic comment through that website. The Commission will consider all comments that regulations.gov forwards to it.

A comment filed in paper form should include the “Emerging Health Care Competition and Consumer Issues – Comment, Project No. P083901” reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-135 (Annex F), 600 Pennsylvania Avenue, NW, Washington, DC 20580.

The Federal Trade Commission Act (“FTC Act”) and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives, whether filed in paper or electronic form. Comments received will be available to the public on the FTC website, to the extent practicable, at <http://www.ftc.gov/os/publiccomments.htm>. As a matter of discretion, the Commission makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC’s privacy policy, at <http://www.ftc.gov/ftc/privacy.shtm><http://www.ftc.gov>.

FOR FURTHER INFORMATION CONTACT: Michael Wroblewski, Bureau of Competition, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580; telephone (202) 326-2435; e-mail: mwroblewski@ftc.gov. Detailed agendas for the workshop will be available on the FTC Home Page (<http://www.ftc.gov>).

SUPPLEMENTARY INFORMATION: Issues arising from the application of competition and consumer protection law to health care have tremendous significance for

the U.S. economy and consumer/patient welfare. The 2004 Federal Trade Commission and Department of Justice Report, “Improving Health Care: A Dose of Competition” described the economic significance of health care to U.S. productivity. It has become even more so in the intervening four years. The Commission has an important role to play in health care markets through its missions of maintaining competition and protecting consumers.

The Commission intends to focus on two emerging areas that implicate both its competition and consumer protection mission: (1) competition provided by developing an abbreviated regulatory approval pathway for follow-on biologic drugs;² and (2) competition among health care providers based on quality information. Through these workshops and roundtables the Commission intends to analyze the potential impacts on the marketplace of various policy options in these two areas. ³

I. Competition Issues Involving Follow-on Biologic Drugs

A. Regulatory Exclusivities and Follow-on Biologic Drug Competition

One of the central questions in establishing an abbreviated regulatory approval pathway for follow-on biologic products involves how to strike the right balance between regulatory exclusivity periods and competition to spur the development of new,

² Follow-on biologic drugs refer to those drugs that are sufficiently similar to an approved or referenced biologic product to permit the follow-on applicant to rely on existing scientific knowledge about the safety and effectiveness of the referenced biologic product to obtain approval of the follow-on product. A follow-on biologic drug is not necessarily interchangeable or substitutable at the pharmacy level with the referenced drug product.

³ On May 2, 2008, the FTC responded to questions from the Subcommittee on Health of the Committee on Energy and Commerce relating to the creation of a pathway for FDA approval of follow-on biologic products. *See* http://energycommerce.house.gov/Press_110/110-ltr.050208.respto040308.FTC.pdf.

improved, and follow-on biologic drug products. The present regulatory scheme governing approval of non-biologic (or small molecule) generic pharmaceutical drug products offers innovator companies incentives through regulatory exclusivities that provide some degree of protection from new competition in the marketplace, separate and apart from whatever patent protection may exist. In addition, first generic drug applicants are eligible for a 180-day exclusivity period during which other generic drug applicants are precluded from receiving FDA approval to enter the market. The question arises whether, or to what the extent, these regulatory incentives should be adopted in creating a pathway for the approval of follow-on biologic drug products. The FTC invites comments on the following questions.

1. What is the likely competitive effect of the market entry of a follow-on biologic competitor? Are there empirical models that predict the nature of this competition based on existing biologic drug product competition? How has competition developed between referenced and follow-on products in European markets? Would referenced product manufacturers lower their prices, offer discounts, and/or engage in enhanced marketing activities?
2. What is the likely impact of a follow-on biologic product being designated “interchangeable” (*i.e.*, receiving an approval that would permit pharmacists, without physician authorization, to fill a prescription for the referenced product with the follow-on product)? What are the prospects for the use of “authorized follow-on biologics” in these circumstances? Do the answers to these questions differ based on the type of biologic product involved?

3. What competitive concerns are raised by joint research and development, supply, licensing, marketing, and distribution agreements between referenced biologic manufacturers and their follow-on biologic competitors? What would be the likely impact of a requirement that agreements between referenced drug product manufacturers and follow-on biologic applicants be filed with the FTC and the Department of Justice Antitrust Division?
4. How would the prospect of competition from follow-on biologic drugs influence research and development for new biologic drugs, improvements to existing biologic drugs, and the timing and rollout of new and/or improved biologic drugs? Does the market experience with non-biologic generic pharmaceutical drug products provide insights into these issues?
5. How does the method used by Medicare for reimbursement of biologic drug products affect pricing and competition of referenced biologic products? What factors are important for this effect and why? How would the Medicare reimbursement system likely affect prices for both the referenced and follow-on biologic products? For example, does Medicare reimburse Part B drugs, including biological drugs, based on the Average Sales Price of all the biological drugs whose National Drug Codes (NDCs) reference the same Biologic License Application (BLA)? If so, how would a follow-on biologic drug that does not reference the BLA of the referenced drug affect the Medicare reimbursed price for referenced drug product? How will these and other Medicare reimbursement methodologies likely affect models of price competition after follow-on biologic drug entry?

6. How are the patent portfolios claiming biologic drugs similar or dissimilar to the patent portfolios that claim small molecule (nonbiologic) drugs approved under the federal Food, Drug, and Cosmetic Act (FDCA)?
7. Are the regulatory exclusivities currently provided to pharmaceutical drug products in the FDCA appropriate for new biologic drugs and/or significant improvements to existing biologic products? Are they appropriate for specific types of biologics? Why or why not?
8. What are the appropriate factors to consider when determining the optimal length of regulatory exclusivity periods for biologic drug products? Do these factors change based on the type of referenced product involved, the extent of competition facing the referenced product, or patent portfolios claiming the referenced product, and if so, how?
9. How does the European Medicines Agency's approach to regulatory exclusivities in its abbreviated regulatory approval pathway for follow-on biologics inform the U.S. approach?
10. Is a marketing exclusivity period necessary to encourage companies to develop follow-on biologics and to seek their approval by the FDA? If so, why, and how should such an exclusivity period be structured?

B. Patent Dispute Resolution Issues

One of the features of the Hatch-Waxman Amendments to the FDCA is a regulatory structure that encourages the initiation of patent litigation early in the FDA approval process for a generic drug application that challenges a patent claiming the innovator's drug product (a Paragraph IV application). Since 1998, the FDA has faced

many fact situations that have required the agency to interpret this aspect of the Hatch-Waxman regulatory scheme. Many of these interpretations have been challenged by industry participants, resulting in substantial court review of the FDA's decisions. Moreover, the FTC has taken numerous enforcement actions against brand and generic drug manufacturers that have allegedly abused this regulatory structure.⁴ In light of these experiences, the FTC invites comments on the following questions and topics.

1. Would it be important to have the litigation of any patent disputes proceed concurrently with the abbreviated FDA approval process for follow-on biologics? Why or why not? What has been learned from the experience under Hatch-Waxman about the incentives necessary to encourage early resolution of patent issues?
2. How long might the approval process for a follow-on biologic application take? What factors might influence this timing?
3. How might differences between patent portfolios for small molecule drugs and biologics affect patent litigation involving follow-on biologics? How long might patent litigation involving a follow-on biologic product take?
4. When is it in the interest of a referenced biologic drug manufacturer to resolve patent issues prior to marketing by a follow-on applicant? When is it in the interest of a follow-on biologic applicant to resolve patent issues prior to marketing its follow-on biologic? When is it in the interest of either party to resolve patent issues following commercial marketing of the follow-on product?

⁴ See FTC, Overview of FTC Antitrust Action in Pharmaceutical Services and Products (March 2008), *available at* <http://www.ftc.gov/bc/0608rxupdate.pdf>.

5. What are the legal impediments facing a follow-on biologic applicant that has not been sued for infringement to obtaining a declaratory judgment on patent infringement or invalidity issues prior to commercial marketing of its follow-on product?
6. Are regulatory exclusivities needed to encourage follow-on biologic applicants to challenge patents? Why or why not?
7. What opportunities will biologic drug manufacturers and follow-on applicants have to manipulate proposed new regulatory obligations (*e.g.*, application notification obligations, declarations of patents claiming biologic drugs, etc.) and exclusivity periods surrounding a concurrent patent resolution process? What are the prospects for the improper use of citizen petitions to delay approval of follow-on biologic applications?
8. How might referenced biologic product manufacturers and follow-on biologic applicants structure patent settlement agreements given the competitive dynamics arising from the marketing of follow-on biologic drugs? What incentives might exist for these companies to enter anticompetitive settlements? Should patent settlement agreements be filed with the antitrust agencies? What would be the likely effect of the filing requirement on settlements?

II. Competitive Significance of Health Care Quality Information

Competition in health care markets is enhanced when purchasers have information to help evaluate the cost and quality of the services purchased. The 2004 Health Care Report found, however, that information regarding health care prices and quality is often difficult to measure and obtain and is not necessarily reliable. A 2008

FTC Workshop on Innovations in Health Care Delivery considered ongoing issues about health care price and quality transparency. Panelists at the 2008 Workshop discussed the potential importance to consumers of relevant price information, including out-of-pocket price information. Also discussed were forms of transparency that may be anticompetitive. For instance, public disclosure of confidential contract rates between providers and payers could be anticompetitive because it could foster coordinated pricing. The FTC seeks to build on its 2008 Workshop to explore further the competitive significance of qualitative health care information from the purchasers' viewpoint (*i.e.*, the demand side). The FTC will explore whether or how quality information can be used to help purchaser decision making. The FTC will examine the extent to which there is demand is for high quality health care, the attributes of quality information that motivate purchasers to select high quality providers, and the ramifications of quality-based competition on the availability of health care. Along these lines, the FTC will explore whether providers delivering high quality services are rewarded with more business (and/or greater revenue) and whether those failing to do so either improve or are penalized with less business (and/or lower revenue). In this context, purchasers include consumers, employers, insurers, hospitals, doctors, and others who can use quality information in their decision making. The FTC also will examine the costs and benefits of different federal policies that could be used to facilitate the measurement, collection, and reporting of health care provider quality information to these various purchasers.

The FTC invites comments on the following issues and topics set out below. The FTC encourages comments that analyze the results of recent experiments, demonstration

projects, and initiatives designed to report health care quality measures to various types of purchasers.

A. Purchaser Decision Making and Quality Information

1. What decisions do quality information help different types of purchasers make?
2. What are the relevant times at which purchasers make health care decisions? What quality information about health care services and providers should be presented at these critical junctures?
3. What quality information is the most competitively significant for different types of purchasers? Are different types of data (*e.g.*, licensing information, compliance with process measures, customer satisfaction, outcomes, outcomes per dollar spent) appropriate for different purchasers and purchaser decisions? How should any differences in measurement of the same provider or service (over the same time frame) be reconciled?
4. Does health care quality vary based by medical condition, provider, and patient? Does it vary over time? If so, how should quality measures be adjusted to take these differences into account?
5. What information is needed to measure the efficiency of a provider? What is the proper weighting of quality and resource use in an efficiency measure?
6. How broad a range of differences among health care providers and services is needed to motivate purchasers to switch service providers?
7. How should regional variations be accounted for in showing the results of quality measures? Should local, state, regional, or national benchmarks be used to show differences among service providers? Why or why not?

8. How does the framing of quality information affect the purchasers' decisions? Do symbols and summaries affect purchaser understanding of health care quality information?
9. What has been learned from public and private quality reporting initiatives that can aid the competitive process?
10. What are the tradeoffs between quality-based competition and the availability of health care?

B. Barriers to Developing and Implementing Quality Measures

1. What barriers – clinical, marketplace, regulatory, or other – restrict the measurement, collection, and reporting of health care quality information? Can health care quality be measured such that it is of value to purchasers in their decision making?
2. Do providers and insurers have business reasons to develop and implement public reporting of quality measures?
3. How should quality measurements deal with organizational variation on the supply side (e.g., solo physician practitioners, small physician groups, integrated physician groups, etc.). If so, how should the measures be adjusted to consider this variation?
4. How does the development of reimbursement and payment reform affect the development of quality measurements?
5. Several private and public entities have developed standards to measure health care quality. Are concerns about provider capture of these organizations relevant in this context?

C. Federal Policies to Facilitate Quality Information Collection and Reporting

1. What federal policies can help overcome any marketplace barriers to the measurement, collection, and reporting of quality information?
2. How can government use its role as a payer (*e.g.*, Medicare, Medicaid) to facilitate the development and use of quality information more broadly?
3. What are the costs and benefits of a single entity developing the quality measures, collecting and analyzing the data, and reporting the results? What are the costs and benefits of governmental involvement in these activities?
4. How should federal, state, and private sector efforts to measure and report on health care quality be harmonized so that purchasers obtain the benefits of cost and quality information?

By direction of the Commission.

Donald S. Clark
Secretary