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BY ELECTRONIC SUBMISSION

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue NW
Washington, DC 20580

Re: Authorized Generic Study, FTC Project No. P062105

Dear Secretary:

On behalf of PhRMA, I am enclosing comments on the FTC's proposed study of authorized generics. We appreciate your attention to this matter.

Sincerely,

Michael Cowie

cc: Diane E. Bieri
PhRMA General Counsel

PhRMA Comments to

the Office of Management and Budget and the Federal Trade Commission

Authorized Generic Drug Study

FTC Project No. P062105

June 4, 2007

PhRMA

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INTRODUCTION

The Pharmaceutical Research and Manufacturers of America ("PhRMA") hereby submits comments to the Office of Management and Budget's ("OMB's") Office of Information and Regulatory Affairs ("OIRA") and the Federal Trade Commission ("FTC"). These comments concern the information needed for an empirical study analyzing the competitive effects of authorized generic drugs.

The FTC published its initial proposed information requests in March 2006.[1] In response to comments from PhRMA,[2] as well as others, the FTC has made several material modifications to the proposed information requests.[3] PhRMA commends the FTC for the initial changes, which will help lower costs borne by respondents and focus the study more directly on the economic impact of authorized generics. For example, the FTC has eliminated the request for documents that relate generally or broadly to competition with generic drug companies. It also has cut back the search for documents at the vice president level and below.

In some respects, however, the modified Information Collection Request ("ICR") now proposed by the FTC still lacks practical utility under the Paperwork Reduction Act ("PRA"). The ICR is not limited to requests for empirical data or even to requests for data and documents discussing actual competition or events in the marketplace. Rather, the requests encompass documents speculating about "possible" competition that might occur in the future. The FTC's notice indicates that some of the documents requested under the ICR have only a potential use for

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[1] FTC First Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062195, Mar. 29, 2006, www.ftc.gov.

[2] PhRMA Comments on Proposed Information Requests, June 5, 2006, www.ftc.gov.

[3] FTC Second Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062195, at 10, Apr. 30, 2007, www.ftc.gov (eliminating requests for documents relating generally to competition and generic entry); *id.* at 11 (eliminating language that would reach "any document" and instead focusing on "studies, surveys, analysis, and reports"); *id.* at 12 (eliminating requests for documents prepared "by or for" vice-presidents); *id.* at 13 (eliminating the requirement to provide a detailed catalog of information on each responsive document and instead requiring sorting by drug); *id.* at 14-15 (reducing the number of drugs covered); *id.* at 18 (eliminating the request for cost data from brand name drugs); *id.* at 20 (eliminating the request for each company to provide IMS data).

the stated purpose of the collection.[4] Despite the modifications FTC has made, these far-reaching document requests are not tailored to provide reliable, verifiable information that meets the study's economic objectives, as well as the requirements of the PRA.

The burden of obtaining email, memoranda, or other speaking documents from many companies far outweighs the burden of obtaining the more useful data -- primarily pricing and profitability data.[5] The FTC's $10.2 million burden estimate, attributed largely to document collection, appears significantly understated. Responding to the ICR as written would require companies to search the files of dozens, perhaps hundreds, of employees and advisors of each brand name drug company. The size of the search group is a key driver of costs,[6] and has not been estimated or accounted for in a meaningful way. The FTC has not accounted for several other significant cost elements in arriving at its $10.2 million burden estimate.

We respectfully submit that OIRA should correct these deficiencies during its review of the ICR. Fortunately, the data and methodology exist to conduct a useful, reliable, and accurate study. The subject matter of the proposed study—the competitive effect of authorized generics—has been the source of speculative complaints for over ten years by incumbent generic drug companies and others seeking to limit price competition.[7] In response to this rhetoric, PhRMA

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[4] *Id.* at 17 ("Brand name company documents could further elucidate the likely effects of AGs. . . .").

[5] *Id.* at 26 (the FTC "anticipates that the majority of burden hours will result from document production").

[6] *See* FTC Reforms to Merger Review Process, at 11, Feb. 16, 2006, www.ftc.gov (discussing critical impact of search group size on costs); Justice Department, Background Information on the 2006 Amendments to the Merger Review Process Initiative, at 7, www.usdoj.gov/atr (same).

[7] *See, e.g.,* All About Generic Pharmaceuticals, Now the Big Drug Makers Are Imitating their Imitators, N.Y. Times, Sept. 20, 1992 (chairman of generic drug company claims in 1992 that authorized generics are "a ploy by the brand-name companies to try to drive us out of business"); The Drugmakers vs. Trustbusters, Business Week, Sept. 4, 1994, at 67 (another chairman of a generic drug company states in 1994 that "the goal [of authorized generics] is to drive the generics out of business"); Testimony of Heather Bresch, Sr. V.P. of Corp. Strategic Dev., Mylan Laboratories, U.S. Senate Comm. On Aging, July 20, 2006 (generic company executive claims in 2006 that authorized generics are sold at prices that "gut generic returns"); The War on Generics -- Part I, The RMP Report, at 10, Sept. 2006, www.therpmreport.com (GPhA president claims in 2006 that authorized generics "will lead to dire consequences to the generic industry"); Feds Look Into Battle Over Authorized Generics, Investor's Business Daily, Aug. 14, 2006 (GPhA president claims that authorized generics will enable brand companies "to squeeze out generic competition").

has commissioned economic studies showing that authorized generics have led to lower prices for consumers and that entry has continued at a rapid rate.[8] For its own part, the FTC has gathered information in the context of data-intensive merger investigations, and has found that authorized generics have played a critical role in constraining generic drug prices and has taken enforcement action to preserve the benefits of competition from authorized generics.[9]

PhRMA welcomes a properly designed FTC study of the actual competitive effect of authorized generics because the results will further advance public understanding of how authorized generics help consumers. The study should be grounded in accurate, current, and complete empirical data so as to comply with the PRA and so as to provide useful information to the FTC and the public.

I. BRAND NAME DRUG COMPANY DOCUMENTS THAT DO NOT CONTAIN EMPIRICAL DATA LACK PRACTICAL UTILITY

In responding to the FTC's original information requests, PhRMA contended that email, memoranda, or other speaking documents will not further the goals of a data-driven study on competitive effects. Unfortunately, the FTC largely dismissed these concerns in its notice setting forth its revised ICR, referring to PhRMA's comments on this point as "a restatement of its concerns about burden."[10] To the contrary, PhRMA's concerns about the nature of the

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[8] For PhRMA commissioned economic studies, *see* Berndt et al., Do Authorized Generic Drugs, Deter Paragraph IV Certifications? Recent Evidence, Working Paper, Apr. 17, 2007, www.phrma.org; IMS Consulting, Assessment of Authorized Generics in the U.S., Spring 2006, www.phrma.org; Howrey LLP & CapAnalysis, Authorized Generics: Economic Analysis Shows Substantial and Lasting Price Reductions, May 7, 2007, www.howrey.com. For other useful recent economic studies, *see* Hasset & Shapiro, The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals, Apr. 2007, www.authorizedgenerics.com; Berndt et al., Authorized Generic Drugs, Price Competition and Consumers' Welfare, Health Affairs, Vol. 26 No. 3 at 790, May/June 2007.

[9] *In the Matter of Teva Pharmaceuticals Ltd. and Ivax Corp.*, FTC Docket No. C-4155, File No. 051-0214, Decision and Order, Jan. 2006, www.ftc.gov (by threatening to reduce independent competition from authorized generics, the merger "increase[d] the likelihood that customers would be forced to pay higher prices"); *In the Matter of Watson Pharmaceuticals, Inc. and Andrx Corp.*, Docket No. C-4172, Complaint ¶¶ 9, 12, Oct. 31, 2006, www.ftc.gov (treating authorized generics as competing independent competitive forces in generic drug markets); *see also* Merger Enforcement in the Generic Drug Industry, 20 Antitrust Health Care Chronicle 1, 19, Mar. 2006 (discussing significance of FTC findings about authorized generics in Teva/Ivax).

[10] FTC Second Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062195, at 8, Apr. 30, 2007, www.ftc.gov.

information sought in the ICR stemmed from its desire to focus the FTC's requests on information that will yield the most accurate and reliable data for the FTC's study. PhRMA continues to maintain that brand-name company speaking documents lack practical utility for this study.

A. Data, Not Documents, Fully Support the Needs of the Study

As conceived, the proposed study would analyze the actual competitive effects of authorized generics in the marketplace. A Congressional request called for a study of "*the impact* of so-called 'authorized generics' on competition in the prescription drug marketplace."[11] The FTC has explained to Congress that this study will "build on the economic literature about *the effect* of generic drug entry on prescription drug prices."[12] According to the FTC, "[t]he proposed study would include a more robust and up-to-date analysis of *the competitive effects* of authorized generics based on actual company data."[13]

To conduct this effects-focused study, the FTC proposes collecting data from 190 drug companies. The FTC proposes collecting and analyzing data on the pricing of brand name drugs and the pricing of generic drugs both with and without competition from authorized generics. As the FTC has explained, the pricing data will enable it to analyze the "short-term" competitive effects of authorized generics.[14]

The FTC also proposes analyzing data to assess the "long-term" competitive effects of authorized generics, focusing on whether authorized generics have led to an observable decline in

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[11] FTC First Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062195, at 3, Mar. 29, 2006, www.ftc.gov (quoting letter from Senators Grassley, Leahy, and Rockefeller) (emphasis added).

[12] FTC, Congressional Budget Justification, Fiscal Year 2007, at 10, Feb. 6, 2006, www.ftc.gov (emphasis added).

[13] FTC First Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062195, at 3, Mar. 29, 2006, www.ftc.gov (emphasis added).

[14] FTC Second Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062195, at 3, Apr. 30, 2007, www.ftc.gov.

entry.[15] It proposes analyzing data on the rate of ANDA filings (Abbreviated New Drug Applications) by generic drug companies.[16] It also seeks generic drug company cost and profitability data "to evaluate the effects of AGs on profitability and return on investment, particularly during the 180-day exclusivity."[17] This cost and profitability data will be useful "for evaluating generic companies' incentives to file ANDAs and make paragraph IV certifications" and thereby help assess the "long-term effects" of authorized generics.[18]

In this respect, the FTC has explained clearly how the requested data has practical utility for evaluating the competitive effects of authorized generics. It has not, however, provided a justification to collect documents, particularly documents from brand name drug companies that are not the focus of the entry analysis.

Documents generated by various employees of brand name drug companies will not provide robust information for an economic study on the short-term price effect of authorized generics. Nor will email, memoranda, or other speaking documents provide robust evidence on the long-term effects or effects on entry. They are unlikely to provide high quality information on the rate of ANDA filings by generic drug companies or on the profitability of entry by generic drug companies.

B. The FTC Recognizes that Brand Name Company Documents Do Not Have Practical Utility

It is apparent from the FTC's analysis that brand name company documents are, at most, tangential to the study. The FTC has described the generic company documents as "the most

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[15] *Id.*

[16] *Id.* at 17 ("Quantitative data on recent filings of ANDAs with paragraph IV certifications should also be relevant to the long-term picture, because recent filings have been made in light of the current climate regarding the marketing of AGs.").

[17] *Id.* at 18.

[18] *Id.* at 17 (stating that "return on investment" data is "more relevant to the long-term effects of AGs on ANDA-generic companies' incentives to file ANDAs and challenge patents").

informative,"[19] as "the most useful,"[20] as "essential,"[21] and as "necessary."[22] Indeed, documents describing how generic companies evaluate entry into new markets are, by necessity, in the hands of the generic companies. According to the FTC, generic company documents concern the long-term effects of authorized generics on entry by generic drug companies. In this respect, the FTC has explained clearly how the requested information has practical utility for evaluating the competitive effects of authorized generics.

In contrast, the value of speaking documents from employees of brand name companies is admittedly far less certain. The FTC contends that brand name company documents "could" have secondary or indirect relevance. These documents "could further elucidate the likely effects of AGs on generic company decisions to challenge patents,"[23] "should provide insight into the likely effects of AGs,"[24] and "should shed light."[25] The FTC further characterizes such documents as "relevant": "While generic company documents may be the most informative as to generic companies' financial incentives to enter and challenge patents, brand-name . . . documents . . . are relevant."[26] These terms clearly indicate that the FTC finds the information may, at best, be potentially helpful. Any statements in brand name company documents about generic company entry decisions necessarily would reflect second-hand or third-hand information, if not pure speculation, and are therefore of extremely limited use.

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[19] *Id.* at 12.

[20] *Id.* at 14.

[21] *Id.* at 17.

[22] *Id.*

[23] *Id.*

[24] *Id.* at 12.

[25] *Id.* at 16.

[26] *Id.* at 12.

That the documents may be "relevant" or "could" elucidate is not enough to justify these information requests. The operative legal standard under PRA is not mere relevance.[27] To establish practical utility under the PRA, the agency must establish "the actual, not merely the theoretical or potential usefulness to or for an agency . . . . "[28] The FTC must demonstrate to OIRA and the public that the documents are "necessary" and useful for the study.[29] The FTC has not made a showing that these documents are necessary rather than potentially helpful or instructive. At most, the documents could or might shed some light on the subject matter of the empirical study. Under these circumstances, the ICR does not meet the standards of practical utility and should be further modified to eliminate the requirement to produce brand name company speaking documents.

C. Documents That Offer Nothing More Than Speculation About Possible Future Competition Will Not Provide Reliable Information

It is logical that FTC would be hard-pressed to demonstrate the practical utility of speaking documents, since such documents are inherently subjective and speculative. If any requests for speaking documents are authorized, they should be targeted only on documents containing historical analyses or studies of actual competition and thus could have some measure of utility. In other words, any document requests should be limited to analyses of relevant events that have in fact occurred in the marketplace. Documents about possible future competition lack sufficient utility and quality to be meaningful, and should not be targeted for this data-driven study.

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[27] 5 C.F.R. § 1320.3(l).

[28] *Id.*

[29] 5 C.F.R. § 1320.5 (e) ("OMB shall determine whether the collection of information . . . is necessary"); *see also* OMB, Guidance on Agency Survey and Statistical Information Collections, at 9, Jan. 20, 2006, www.omb.gov ("agencies must also justify why the information is needed").

The proposed requests cover documents discussing "the marketing or *possible* marketing" of authorized generics in response to "current or *future* generic competition."[30] These documents would contain individual speculation about possible marketing of authorized generics in response to potential future competition that may never occur. Documents about possible competition will not provide reliable and accurate information on the actual price effect in the marketplace of authorized generics. Nor will such documents reliably show whether generic drug company entry has become unprofitable as a result of authorized generics.

In fact, federal courts in antitrust matters have long recognized the limited value associated with select sound bites or "tidbits" in company files that relay subjective assessments of future competition.[31] In particular, courts often warn that internal company documents expressing certain business or competitive "desires" or future hopes are improper for use in economic analysis.[32] As one court explained, "[t]raipsing through the warehouse of business . . . both increases the costs of litigation and reduces the accuracy of decisions."[33] "Colorful" documents can be "misleading" and do not serve well to answer the "real economic questions" involved in antitrust or competition law matters.[34] These principles certainly apply in the case of industry-wide economic studies of competitive effects.

Market entry decisions are based on a multitude of factors. Speaking documents prepared by internal employees of one company about the competitive entry decisions of another company

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[30] Brand Name Drug Company Special Order, at No. 27, www.ftc.gov (emphasis added).

[31] *R.J. Reynolds Tobacco Co. v. Cigarettes Cheaper!*, 462 F.3d 690, 696 (7th Cir. 2006) (indicating that "tidbits" uncovered during discovery will not support a predatory pricing claim); *AA Poultry Farms, Inc. v. Rose Acre Farms, Inc.*, 881 F.2d 1396, 1402 (7th Cir. 1989) (dismissing the value of "lawyers rummag[ing] through business records seeking to discover tidbits").

[32] *See, e.g., Henry v. Chloride, Inc.*, 809 F.2d 1334, 1344 (9th Cir. 1987) ("This Court is among those that has recognized the hazards of using evidence of desire to prevail competitively to forecast economic harm. . . . Evidence of intent alone can be ambiguous or misleading.").

[33] *AA Poultry Farms, Inc. v. Rose Acre Farms, Inc.*, 881 F.2d 1396, 1402 (7th Cir. 1989).

[34] *Id.*

are inherently speculative and of limited use. Forward-looking comments made by company representatives are difficult to assess and evaluate in the context of an industry-wide empirical study. Unlike pricing and profitability data, such comments are inherently subjective, cannot be reliably aggregated and weighted, and are unlikely to support the study's quantitative objectives. Because of the tenuous or merely theoretical relationship between the documents and the purpose of the study, the FTC carries a heavy burden under the PRA of showing how the speaking documents fit the study design.

However, the FTC does not explain the relationship between the speaking documents and the study design; nor does it explain how it will weigh qualitative information in the midst of an otherwise quantitative assessment. Under the PRA, OIRA has found that study designs lack practical utility if they "can reasonably be expected to yield ambiguous and/or nongeneralizable results because of ambiguous survey questions and unduly biased methodologies and statistical frames . . . . "[35] While independent scientific or economic literature supports the use of quantifiable data, the value of speculative documents about potential future events has not been demonstrated to be reliable or accurate for an economic industry study.

The PRA instructs the OMB Director to "maximize the practical utility of and public benefit from information collected by or for the Federal Government."[36] Through the terms of clearance to the ICR, OIRA should carry out this obligation by approving the collection of information with the condition that the FTC cannot seek production of forward-looking commentary from brand-name drug companies. In other words, any document requests should be limited to analyses of events that have in fact occurred in the marketplace.

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[35] The Paperwork Reduction Act of 1995: Implementing Guidance, Draft at 39, Feb. 3, 1997.

[36] 44 U.S.C. § 3504(c)(4).

II. THE BURDEN OF RESPONDING WILL LIKELY FAR EXCEED THE FTC ESTIMATES

The FTC proposes submitting the information requests to 190 drug companies.[37] It has estimated that "the cumulative hours burden to produce documents and prepare the response sought will be approximately 40,780 hours"[38] and that the total cost will be about $10.2 million.[39]

While the $10.2 million estimate appears significantly understated, incurring costs even at this level is not justified when considering "that the majority of burden hours will result from document production."[40] Compared to the pricing and profitability data, the requested documents unquestionably have much lower value for the proposed economic study. Preparing the least useful information will therefore account for most of the burden, thereby negating the PRA objective of maximizing practical utility and minimizing the burden.

The $10.2 million cost estimate is not justified (given that documents account for most of the costs) and appears significantly understated. In estimating the burden, the FTC stated that "[t]he time period . . . now begins on Jan. 1, 2002 or 2003, depending on company type, and ends on April 3, 2006."[41] However, the FTC has added an information request covering another sixteen month period -- from January 1, 2006 to April 29, 2007.[42] It has not accounted for the cost of responding to documents requests spanning this additional time period. This omission alone could raise the costs well beyond the estimated $10.2 million.

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[37] FTC Second Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062195, at 26, Apr. 30, 2007, www.ftc.gov.

[38] *Id.*

[39] *Id.* at 27.

[40] *Id.* at 26.

[41] FTC Reforms to Merger Review Process, at 25-26, Feb. 16, 2006, www.ftc.gov.

[42] Brand Name Drug Company Special Order at No. 30, www.ftc.gov.

Moreover, the FTC's analysis does not fully take into account the complexity and cost associated with the preservation, collection, and production of electronically stored information. The companies subject to the FTC's requests maintain computing systems with thousands of work stations, servers, and application systems. Technology has made it easier to create and maintain email and other documents. Indeed, the FTC has previously stated that "advances in technology . . . have resulted in companies producing and retaining substantially more documents."[43] It has found that the "lower costs of storing electronic documents and the ubiquitous use of computers have substantially increased the number of electronic documents that firms produce and retain."[44] In this current environment, "complying has become even more costly, primarily due to . . . fundamental changes . . . in technology."[45]

Compared to data, documents are more costly to search for and produce because they are not typically maintained in one central place or computer system, but rather distributed across work stations, servers, and other data stores. The more useful data is likely to be maintained by companies in centralized databases. Extracting and organizing data is in most instances a less burdensome process.

A. The Search Group Has Not Been Estimated and May Be Large

In estimating costs, the FTC has stated that it "seeks only high-level documents . . . ."[46] The proposed document requests, however, cover documents (1) from "the files" of the senior vice president with product line responsibility and (2) from the files of anyone that maintains responsive information prepared "by or for" any company officer or director. The search group for responsive documents prepared "by or for" any officer or director will necessarily include

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[43] FTC Reforms to Merger Review Process, at 2, Feb. 16, 2006, www.ftc.gov.

[44] *Id.* at 6.

[45] *Id.* at 5-6; *see also* Justice Department, Background Information on the 2006 Amendments to the Merger Review Process Initiative at 1, www.usdoj.gov/atr.

[46] FTC Second Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062195, at 26, Apr. 30, 2007, www.ftc.gov.

many other employees and could be read to extend to agents such as outside consultants.[47] Absent further refinements or limitations on scope, companies will be forced to search the files of a significant number of individuals in order to comply with these requests.

Our analysis of publicly-available information for brand-name companies shows that during the relevant time period companies typically had about 30 officers or directors. Officers or directors will have more people reporting to them throughout their companies. There may be dozens of employees interacting with or reporting to a single company officer. Thus, documents prepared "by or for" an officer or director could reside in the files of hundreds of company employees and advisors.

The FTC has recognized that "the size of the search group is one of the most important determinants of total costs."[48] To limit the cost of complex antitrust merger investigations, the FTC has created a presumptive limit of 35 individuals for the search group and the Department of Justice has limited the search group to 30.[49] The pending proposal does not place any numerical limits on the size of the search group, and relies on the far reaching "by or for" language. This language is likely to lead to a large search group, as companies will need to cast a wide net to ensure that documents created "for" officers or directors are captured. In these circumstances, the costs almost certainly will be much larger than the estimated $10.2 million.

B. The FTC Underestimated the Hours Likely To Be Incurred

The FTC has stated that its "initial hour burden estimates are consistent with previous PRA [Paperwork Reduction Act] estimates" without identifying or describing the previous

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[47] Statement of Basis and Purpose, Premerger/HSR Act, Aug. 30, 1978, www.ftc.gov.

[48] FTC Reforms to Merger Review Process, at 11, Feb. 16, 2006, www.ftc.gov.

[49] *Id.*; *see also* Justice Department, Background Information on the 2006 Amendments to the Merger Review Process Initiative at 7, www.usdoj.gov/atr.

supporting estimates.[50] The FTC appears to rely on historical burden estimates that do not account for the increasing costs of producing large volumes of electronically stored records.

The FTC estimates different levels of incurred hours depending on each company's number of covered drug products. For example, companies with 1-5 drug products will incur 140 hours in document production, according to the estimates. Even if the search group were limited to a specific number of individuals – such as 30 individuals – the FTC's estimate is unrealistically low, as demonstrated below.

1. The Hours Incurred During the Retrieval Phase

For the retrieval phase, companies must understand the multiple sources of electronically stored information and input processes for extracting responsive information. The following areas may need to be searched for each of the individuals who may possess responsive documents: (a) hard drives of their workstations; (b) any shared drive on the network where documents could be located; (c) the email system; (d) any document management system used by the company; and (e) any collaboration site where individuals share records. Most companies do not have enterprise wide search and retrieval capability (because of its cost and the relative infancy of this technology). As a result, legal or IT personnel would need to interview the individuals to understand fully where they maintain potentially responsive information.

Once the interviews are complete, the legal team or IT personnel would then be required to extract the information. Past experience indicates that the retrieval process, including both interviews and extraction, will take about two hours per individual. Even if the search group were limited to 30 individuals, the retrieval process would take approximately 60 hours. Cutting corners during the retrieval process puts a company at risk of penalties for failing to locate email or other sources of responsive materials.

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[50] FTC Second Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062195, at 25, Apr. 30, 2007, www.ftc.gov.

2. The Hours Incurred During the Review Phase

Once extracted, the information would need to be reviewed by company or its counsel for responsiveness. The company or counsel must review the content of all potentially responsive information. Reviewing email traffic for responsiveness can be especially time consuming. At this phase, counsel typically would also catalog responsive information (e.g., sort by drug product), identify privilege records, and prepare privilege logs. They will also need to determine whether responsive materials are subject to pre-existing confidentially agreements or protective orders, and take steps to ensure compliance with those obligations.

While the time incurred during the review process is highly sensitive to the volume retrieved for each individual, it is a rule of thumb that the review process typically takes 5-10 times the amount of time incurred in retrieving. As such, the review process amounts to about 10-20 hours per individual custodian. At the low end, the retrieval costs -- 10 hours of review time per individual or 300 hours for 30 individuals -- will significantly exceed the FTC estimate (138 total hours for companies with 1-5 drug products). A more realistic estimate is that each company will incur about 360 hours (300 hours for the review phase + 60 hours for the retrieval phase), not 140 hours.

The time incurred will be larger for companies with search groups exceeding 30 individuals. Companies with more covered drug products (companies with 6-10 products or companies with 10 or more products) are likely to have larger search groups. The FTC has indicated that 60 companies have more than 6 covered drug products in their portfolios.[51]

The time incurred will necessarily vary by the company depending upon its computer systems, its record retention practices, its e-discovery capabilities, and other factors. There will also be significant variation across individuals within the search group depending on their practices and the volume of potentially responsive materials they maintain. While burden and compliance cost estimates are necessarily imprecise, the FTC estimates do not appear to be

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[51] *Id.* at 12.

grounded in current technological conditions. Nor is there a sufficient explanation of the methodology used to estimate burden (e.g., one that includes the size of the expected search group).

C. Companies Would Need to Implement and Enforce a Litigation Hold Order for Over a Year

Both FTC's initial notice from March 2006 and its more recent notice state that "subsequent to this notice, any destruction, removal, mutilation, alteration, or falsification of documentary evidence that may be responsive . . . may be subject to criminal prosecution."[52] Thus, the FTC expects each company, beginning in March 2006, to implement a program -- often referred to as a litigation hold order -- for preserving and maintaining all responsive information. According to the notices, the companies could risk criminal prosecution for failure to do so.

Developing, implementing, and monitoring a litigation holder order is time consuming and expensive. Company counsel must speak with IT personnel to learn about the company's current information storage architecture, its electronic record retention systems, and database retention systems.[53] Companies will also need to prepare communications for and monitor the recordkeeping systems of individual employees likely to have responsive information.[54] Regular follow up may be necessary to ensure that records are being preserved.[55]

The enforcement of litigation holder orders could be taxing and expensive for company IT departments. Companies will need to develop systems and processes for storing larger volumes of email. Policies providing for automatic deletion of aged email may need to be suspended at least for some individuals or units. Also, companies will need to cease recycling or

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[52] *Id.* at 24.

[53] *Zubulake v. UBS Warburg, LLC*, 229 F.R.D. 422, 432-34 (S.D.N.Y. 2004).

[54] *Id.*

[55] *Id.*; *see, e.g.,* Van Horn, Preserving Electronic Evidence, 41 Tenn. Bar Journal 25, Apr. 2005.

overriding storage tapes. These changes can be expensive depending on the company's storage systems and capacity.

This will be a time consuming process. According to the FTC notices, companies may need to develop and implement a litigation hold order for over a year.[56] The FTC does not appear to have estimated these preservation costs, which are considerable, particularly when accounting for the need to preserve email and other documents.

The FTC's $10.2 million burden estimate is significantly understated. It does not account for the full time period of review. Nor does it reflect any meaningful analysis of the scope of the search group, a key element driving the costs of compliance. Moreover, the FTC's cost analysis overlooks other significant costs, particularly the large costs associated with implementation of a litigation hold order.

III. DOCUMENT REQUESTS SHOULD BE ELIMINATED OR AT LEAST MODIFIED

The FTC has proposed 30 information requests for brand name drug companies.[57] Of these, two requests would require companies to search for and produce email and other speaking documents. These two requests -- 27 and 30 -- are unnecessary for the study. At a minimum, they should be changed to reduce the cost of complying.

Suggested Changes	Reasons for Changes
27. Submit all documents that <u>are in the files of</u> ~~were prepared by or for~~ any officer(s) or director(s) of the Company and/or, if applicable, the marketing entity, or that are in the files of any current or prior Company (and/or marketing entity) senior vice president (or equivalent position) with product line responsibility (during all or part of the period from January 1, 2003-April 3, 2006) for an AG and/or a brand-name drug in the list the Company provided to the FTC in response to Item 6 (or, in the case of unincorporated entities, individuals exercising similar	• Limited utility of future competition documents • Reduced burden in conducting document search and review

[56] Brand Name Drug Company Special Order, at No. 9; FTC First Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, FTC Project No. P062195, Mar. 29, 2006, www.ftc.gov.

[57] Brand Name Drug Company Special Order, www.ftc.gov.

Suggested Changes	Reasons for Changes
functions), as follows. (a) For each AG/brand-name pair identified in the list the Company provided to the FTC in response to Item 6, submit ~~planning~~, decisional~~,~~ or strategy documents prepared from Jan. 1, 2002 to April 3, 2006, including studies, surveys, analysis, and reports (both internal and external), that evaluated, ~~considered,~~ or analyzed (but did not merely refer to) the ~~past~~ marketing ~~or possible marketing~~ of an AG or AGs (as a response to ~~current or future~~ generic competition ~~or for other reasons~~, including but not limited to whether or not to lease or otherwise market a brand-name drug product as an AG drug product; reasons for marketing an AG and/or refraining from marketing an AG; the timing of AG launch relative to a 180-day exclusivity period; the marketing of an AG during 180-day exclusivity; the marketing of an AG in the context of paragraph 4 certifications and settlements of litigation; the marketing of AGs upon expiration of patents or marketing exclusivities claiming a brand-name drug product or its use; and the profitability or other benefits of marketing an AG drug. 30. Submit planning, decisional, or strategy documents dated Jan. 1, 2006-April 29, 2007, <u>located in the files of any officer or director</u>, that discuss the effect(s) ~~or possible effect(s)~~ of the enactment of Section 6003 of the Deficit Reduction Act of 2005, P. 109-171, on the marketing of AGs after Jan. 1, 2007.	• Focus on high-level analyses maintained by officers and directors • Focus on analytical documents, not stray references • Focus on covered drug products

These changes would reduce the costs without eliminating any necessary information.

CONCLUSION

For the foregoing reasons, the proposed information requests should be modified to eliminate unnecessary email or document productions that are unlikely to yield reliable information.