STATEMENT OF COMMISSIONER J. THOMAS ROSCH ON THE ABANDONMENT OF THE ENDOCARE, INC. / GALIL MEDICAL, LTD. MERGER

I fear that my colleagues' Counterstatement misses the forest for the trees. On Friday, Endocare, Inc. abandoned its unconsummated merger with Galil Medical Ltd., "as a result of" the Commission's ongoing investigation.[1] The merger between two small companies involved in developing innovative therapies for prostate and renal cancer was too small to be covered by the Hart-Scott-Rodino Act, but the parties agreed not to close the transaction so long as the Commission was investigating it. As a result of the Commission's failure to conclude its investigation in a timely fashion, the Commission could not and did not find that there is "reason to believe" that this transaction is illegal or that challenging it would be in the public interest. My colleagues do not and cannot dispute this fundamental fact. They also do not claim that there is any evidence sufficient to justify blocking this merger de jure. In blocking this merger de facto (as the Commission by failing to timely conclude its investigation and reach a determination on the merger's legality has now done), I respectfully submit that the Commission acts contrary to its statutory obligation and the public interest.

There is no legitimate reason why the Commission should block this merger de facto by letting the clock run out on the parties' agreement to abandon the transaction if the investigation remained open. The investigation was initiated in late 2008. That is more than six (6) months ago. Although the transaction was not reportable under the Hart-Scott-Rodino Act, there is no basis for supposing that the "subpoena" the Counterstatement refers to was anything other than a broad subpoena that mirrored the Model Second Request. That Model requires the production, inter alia, of electronic documents (like email messages that are not segregated by subject matter).

The parties produced several boxes of hard-copy documents, but declined to produce additional documents on the ground that the burden of search, segregation and production was beyond their means as small companies with severely limited resources. It may be claimed that, as a result, the parties were responsible for the lengthy period that has since elapsed. However, my colleagues do not make that claim and, in any event, it would not be meritorious.

First, I have not seen any indication that the parties' response halted the investigation. For example, I have seen nothing to indicate that the parties' response prevented interviews with a representative number of affected market participants (about the incidence and costs of switching from Endocare to Galil, for example), or investigational hearings. Nor have I seen any description of any documents that support liability.

Second, if the parties' response was deemed to have blocked the investigation, there were available remedies. The Commission could have promptly sent the parties a more tailored document subpoena, targeting documents that would yield information considered critical and

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[1] Endocare states that it has "terminated the Galil Merger Agreement as a result of the failure by the United States Federal Trade Commission to close its investigation into whether the Galil Merger violated certain U.S. antitrust laws, which caused certain conditions to closing of the Galil Merger to become incapable of fulfillment." Endocare, Inc. (Form 8-K) (June 8, 2009).

that the parties could not readily claim did not exist or could only be produced with undue burden and expense. Or, if the broad subpoena was not considered to be unduly broad or burdensome and expensive for the parties, the Office of General Counsel could have brought a subpoena enforcement action in federal district court. I have not seen any indication that either of these things occurred.

Third, to the extent that the Commission blames the parties for the delay on the ground that they had the burden to prove that the merger was not likely to threaten a substantial lessening of competition or the creation of monopoly power in a relevant market, that gets things backwards. To be sure, in the ordinary case, once the Commission proves that a merger is likely to threaten a substantial lessening of competition or to create a monopoly in a relevant market, the burden shifts to the parties to establish that new entry or efficiencies (like innovation) resulting from the merger will justify the lessening of competition created by it. *See United States v. Baker Hughes, Inc.*, 908 F.2d 981 (D.C. Cir. 1990). But where, as here, there is no evidence that gives the Commission "reason to believe" that a merger likely threatens to substantially injure price (or non-price) competition or creates a monopoly in a relevant market in the first place, the burden never shifts to the parties.

In short, this case represents a "poster child" for how protracted investigation of a transaction or practice can result in the Commission failing to determine in a timely fashion whether there is "reason to believe" that a transaction or practice will violate the antitrust laws and the public interest. The Commission simply must do better.

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Because the Office of General Counsel has declined to exercise its discretion under Commission Rule 4.11(h), my description of the facts necessarily must be limited.[2] However, based on what I am permitted to say, these are the facts.

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[2] Unfortunately, OGC did not feel obliged to scrub the Counterstatement so assiduously. As a result, the Counterstatement describes this case in generalities without providing any support for those generalities. For example, it asserts that there were "efforts to work closely with the parties in an effort to obtain relevant information without undue burden" (Counterstatement at 1), without discussing, among other things, whether any targeted subpoena was ever promptly sent to the parties or whether there was a single investigational hearing. Similarly, the Counterstatement asserts that the parties' "self-selected" documents were "insufficient to substantiate the parties' efficiency claims" (*id.* at 2), without identifying the documents that the Counterstatement refers to or discussing whether any of the parties' documents showed that the proposed merger was likely to substantially injure competition or create a monopoly in any relevant market (which, after all, is the threshold issue for the Commission in any merger investigation). And, the Counterstatement asserts that there was an "independent gathering and assessment of additional information from a variety of sources (including numerous interviews with third parties)" (*id.*), without identifying the nature of those "sources" or discussing the extent to which those "interviews with third parties" provided "reason to believe" that the proposed merger would violate the law, and if so, how many of the interviews conducted did so. Indeed, the Counterstatement says nothing about whether those interviewees were even

First, this merger involves the combination of two small companies that make and sell products used for a therapeutic treatment for prostate and renal cancer. Those products consist of consoles and consumables that physicians (principally urologists) administer to provide what is called cryotherapy. That is a form of therapy that combats cancer by freezing it (as opposed to, for example, combating cancer by exposing it to radiation or other consumables that burn it or eliminate it through surgery).

The FDA has approved the marketing and use of cryotherapy products for combating prostate and renal cancer (prostate cancer being the most prevalent form of non-skin cancer in America), and the federal government has assigned codes that those seeking reimbursement for these therapeutic uses can use. The FDA has also approved the use of cryotherapy for use in combating certain other metastasized forms of soft tissue cancers such as liver, lung and bone cancer, but it has not approved marketing cryotherapy products for those uses. Moreover, the federal government has not approved reimbursement codes for the use of cryotherapy products for those purposes. Finally, neither the FDA nor the federal agency responsible for assigning reimbursement codes has approved the use of cryotherapy products for the treatment of any primary forms of cancer other than prostate and renal cancer.

Based upon the parties' representations to me, the merger was designed, at least in part, to enable the parties to finance and engage in research and development and to obtain the approvals necessary to market cryotherapy for cancers other than prostate and renal cancer. There is no basis for believing that Healthtronics, Inc., which Endocare has announced will now acquire it (in lieu of a merger with Galil), has ever engaged in research and development respecting any form of cancer.

Second, it does not currently appear that the merger will threaten to injure consumers by substantially increasing the prices that they pay for cryotherapy. To be sure, the parties appear to be the only two companies that make and market cryotherapy products. However, the purchasers of the consoles are principally hospitals and distributors who furnish the consoles to hospitals via mobile service units. The seller provides those buyers with extensive education and training respecting the use of the consoles and, as a result, pre-sale the buyers are arguably "locked into" the consoles sold by one party or the other. Moreover, the consumables that the parties make and sell for the administration of cryotherapy cannot be used interchangeably with the consoles that each party makes and sells.

Most importantly, the providers of other cancer therapies – which are more popular than cryotherapy – are able to constrain the merged entity in any effort it might make post-merger to charge supra-competitive prices for cryotherapy products. That is the critical question in defining the relevant market in which the parties compete. *See* Horizontal Merger Guidelines § 1.0. In fact, as matters now stand, it appears that cryotherapy has a very small and diminishing share of the market for therapies for prostate or renal cancer, as well as for the other forms of

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representative of the universe of market participants that exists. Under these circumstances, it cannot be expected that any unbiased observer will simply take at face value the Counterstatement's conclusory assurance that this investigation was "diligent, competent, even-handed and professional." (*Id.* at 1.)

metastasized cancers for which cryotherapy can be used (but not marketed). Indeed, I have not seen any estimates of the pre- and post-merger market shares or HHIs in any relevant market. Likewise, I have not seen any estimates of the amount that the parties' shares (or HHIs) will increase as a result of the merger.

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The parties have not fully complied with the Commission's document subpoena, alleging that the burden and expense of searching for, segregating, and producing the documents called for make it impossible for them to do so. Thus, the Commission must weigh the risk that compliance with its subpoenas will be undercut against the public interest in not blocking this transaction. Given the unique circumstances of this case, however, it does not seem that that risk outweighs the public interest.

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In sum, I respectfully suggest that, by blocking this merger de facto, the Commission acts contrary to the public interest and to its statutory authority to block mergers *only* when it has reason to believe that they are illegal. This is especially serious in this case in view of the facts that (1) the Commission has had an investigation of this non-HSR reportable merger open for many months; (2) this case involves the treatment of the leading form of non-skin cancer afflicting Americans (so the Commission had better be especially sure it is doing the right thing); (3) I have seen nothing to indicate that the merger here poses a likely threat of supra-competitive pricing; and (4) I have also seen no evidence that indicates that there is a likely danger that this merger will stifle more or quicker innovation.

I am sad to say this about any Commission matter. However, I will not shrink from self-criticism of the agency either. I just sincerely hope that the Counterstatement is wrong in its assertion that this matter was handled in a fashion that is "fully consistent with the Commission's mission." (Counterstatement at 2.) I have higher aspirations for the agency.